



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Committees Support Division
Scientific Committee Support Department

Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

Disclaimer: This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency

Brief description (or name where available) of the active substance(s)

The product is a cell-based immunotherapy product prepared individually for each patient.

Brief description of the finished product

The medicinal product consists of two compounds, both subcutaneously administered at the same implantation site:

- Encapsulated allogeneic cells secreting GM-CSF.
- Irradiated Autologous tumor cells.

Proposed indication

The initial target indication is malignant solid tumours. These include all cancer tumor types with the exclusion of tumors from hematopoietic origin (such as leukemia, lymphoma, myeloma or myelodysplastic syndromes).

EMA/CAT conclusion

The committee adopted on 25th September 2015 the following scientific recommendation.

On the basis that:



- The product meets the definition of Medicinal product, as described under (b) of Article 1(2) of Directive 2001/83/EC, as it is a combination of substances which may be administered to human beings with a view to modifying physiological functions by exerting an immunological action.
- The product meets the definition of advanced therapy medicinal product, as described under (a) of Article 2(1) of Regulation (EC) No 1394/2007: its first component is a gene therapy medicinal product and its second component is a somatic cell therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC.

A product falling within the definition of a somatic cell therapy medicinal product and a gene therapy medicinal product is considered a gene therapy medicinal product, as described in Article 2(5) of Regulation (EC) No 1394/2007.

- The product meets the definition of combined advanced therapy medicinal product as described under (d) of Article 2(1) of Regulation (EC) No 1394/2007, as it contains cell encapsulation technology, thus incorporates a medical device within the meaning of Article 1(2)(a) of Directive 93/42/EEC, and its cellular part contains viable and non-viable cells.

The EMA/CAT considers that the product falls within the definition of a combined advanced therapy medicinal product.