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Patient Health Protection

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.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Short descriptor (or name when available) of the proposed active substance

The active substance is composed of human islets of Langerhans. They are obtained with a manufacturing process in which the raw material is treated in order to isolate the islets from the rest of the pancreatic tissue.

Brief description of the proposed finished product

Suspension containing human islets of Langerhans, autologous or allogeneic.

Proposed indication

Autologous:
Post pancreatectomy for benign pancreatic pathologies

Allogeneic:
Treatment of severe forms of type 1 diabetes

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EMA/CAT comment

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)

For defining the product as somatic cell therapy product or tissue engineered product it is required that it contains engineered cells as defined in Article 2(c) of Regulation (EC) No 1394/2007. Therefore the product should "contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor."

From the information provided by the Applicant, it is considered that the product is derived from pancreatic tissue by a number of steps that do not constitute substantial manipulation. Moreover, information provided by the Applicant show that the manipulation of the tissue does not alter the biological characteristics and physiological functions relevant for the intended clinical use.

Based on the information provided by the Applicant the CAT considered that there is no change in the biological characteristics of the islets. The cells of the islets do not divide. It is considered that the phenotype and function of the cells contained in the product are not changed.

The product is intended to be used for the same essential function in the recipient and the donor, i.e. pancreatic function.

- Thus, the product does not constitute a somatic cell therapy medicinal product or a tissue engineered products.
- The product does not constitute a gene therapy medicinal product.

Based on the above considerations, it is considered that the product does not fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.

EMA/CAT conclusion

On the basis that:

- the product does not fall neither into somatic cell therapy medicinal products nor of a tissue engineered product
- the product is not gene therapy medicinal product

The Agency/CAT considers that the product does not fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.