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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)

Viable hepatocyte-like human embryonic stem cell-derived cells

Brief description of the finished product

Hepatocyte-like cells are cryopreserved in the freezing solution, solution for injection

Proposed indication

Treatment of inborn liver metabolic diseases like Crigler-Naijar syndrome 1 and for drug-induced acute liver failure such as paracetamol intoxication.

EMA / CAT conclusion

The committee adopted on 28th October 2015 the following scientific recommendation.

On the basis that:

(a) consists of cells 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 (but excluding the manipulations listed in Annex I to Regulation (EC) No 1394/2007);

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(b) the product is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue.

The EMA/CAT considers that the product falls within the definition of a tissue engineered product.