EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Committeess 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)

Cultured human hepatoblastoma cells (HepG2) encapsulated in alginate.

Brief description of the finished product

Human hepatoblastoma cells (HepG2) encapsulated in alginate, expanded to competence and maintained in a fluidised bed bioreactor

Proposed indication

Acute liver failure

EMA / CAT conclusion

The committee adopted on 21st December 2015 the following scientific recommendations.

On the basis that:

- the product fulfils the definition of a biological medicinal product
- the product contains substantially manipulated viable cells

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- the product is used on patients with a view to stabilizing liver function in Acute Liver failure
- the claimed mechanism of action and indication relate to the metabolism of toxins and replacement of proteins
- the viable cells are expanded and maintained in a fluidised bed bioreactor, that can be considered as an integral medical device component

the EMA/CAT considers that the product falls within the definition of somatic cell therapy medicinal product, combined ATMP as provided in Article 2(1) of Regulation (EC) No 1394/2007.