EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance & Committees Division

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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

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

Autologous cord blood nucleated cells.

Brief description of the finished product

Cell suspension for injection.

Proposed indication

Treatment of paediatric brain damage, hypoxic-ischemic encephalopathy, cerebral palsy.

EMA/CAT conclusion

The procedure was finalised on 6 February 2019 for the following recommendation.

On the basis that:

- the product consists of viable human cord blood cells;

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- the cells have not been substantially manipulated;
- the cells are not intended to be used for the same essential function;
- the cells are presented as having properties for regenerating, repairing or replacing a human tissue,

the EMA/CAT considers that the product falls within the definition of a tissue engineered product, as provided in Article 2(4) of Regulation (EC) 1394/2007.