At the European level, where can developers request advice for cell-based products?

**ATMP**

- Developers can request advice to CAT*

**Borderline product**

- Developers usually request advice to CAT as it is the only European regulatory body which can be consulted

**Cell/Tissue transplant**

- Developers can NOT request advice to CASoHO **Expert Group**

**Blood component**

CAT’s procedure to determine whether a cell product falls within the ATMP legal definition

- 1st: type of manipulation
  - Substantial → ATMP
  - Non-substantial

- 2nd: intended use
  - Essential function/s
  - Non-essential function/s → ATMP

Examples of potential misclassification & inconsistencies in the criteria applied by CAT

- Radiolabelling of cells or enzymatic digestion of the pancreas are considered non-substantial manipulations by CAT. In contrast, CAT considers substantial the use of growth factors to maintain the viability of selected cells, or their state of activation for a few hours, as well as enzymatic digestion to dissociate keratinocytes

- CAT equates non-essential function/s with non-homologous use or different anatomical / histological environment

Need to create working groups among CAT and competent authorities for different cell-based products

Risk of broadening the scope of ATMPs and classifying clinical practice as ATMPs

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*CAT: Committee for Advanced Therapies of the European Medicines Agency

**CASoHO: Competent Authorities of Substances of Human Origin (DG Santé – Health and Food Safety)