



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Classification of ATMPs

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An agency of the European Union





Classification of ATMPs

- CAT is operating the ATMP classification procedure **for more than 5 year** and has classified over 100 products
- Outcome of the assessment & summaries of the scientific recommendation on classification of ATMPs are available on EMA webpage
- Reflection Paper on classification of ATMPs (2012) has been updated (2014) to reflect the current thinking of the CAT
 - **on substantial manipulation**
 - **and non-homologous use**



Classification of ATMPs

▪ **Additional changes** have been implemented to clarify the existing concepts

e.g. the boundary between **vaccines against infectious diseases & GTMP** and **criteria for combined ATMPs**