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Advanced therapy medicinal products (ATMPs): regulatory framework, development and marketing authorization in the EU

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Advanced therapy medicinal products (ATMPs) reflect a complex and innovative class of biopharmaceuticals as these products are highly research-driven, characterized by innovative manufacturing processes and heterogeneous in terms of their origin, type and complexity. Therefore, multiple development, scientific and regulatory challenges arise from the nature of ATMPs while bringing these medicinal products to patients, which are often developed by SMEs or non-profit organizations with limited regulatory expertise. As such, awareness on the availability of specific yet flexible access pathways as well as regulatory tools is critical to foster the development and commercialization

of safe and effective ATMPs. This presentation provides an overview of the main ATMPs access pathways in the EU including the hospital exemption, the clinical trial and the marketing authorization framework. Also, the main regulatory tools to support ATMP development and commercialization in the EU are also presented, with particular emphasis on the tasks of the EMA's Committee for Advanced Therapies (CAT), which is responsible for following scientific developments in the field and – among the other tasks - assessing the quality, efficacy and safety data supporting ATMPs' marketing authorizations applications.

Organizzazione
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