

The new European regulation on Health Technology Assessment: what changes for Advanced Therapy Medicinal Products?

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Health Technology Assessment (HTA)?

“A **multidisciplinary process** that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner.”

Article 2.5) EU Regulation 2021/2282

➔ **Evidence-based process enabling relative effectiveness assessment of new/ existing technologies**

Health technology?

“A **medicinal product**, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.”

Article 3.1) Directive 2011/24/EU

➔ **ATMPs are included**

