Contracts for better access to Advanced Therapy Medicinal Products

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Advanced Therapy Medicinal Products

(ATMPs) *Regulation (EC) No. 1394/2007*

- Revolutionary treatments for serious diseases
- Target directly the cause
- Often one-shot treatments
- Expensive (1-2 million €) → Limited patient access

Managed Entry Agreements (MEAs)

are a possible solution

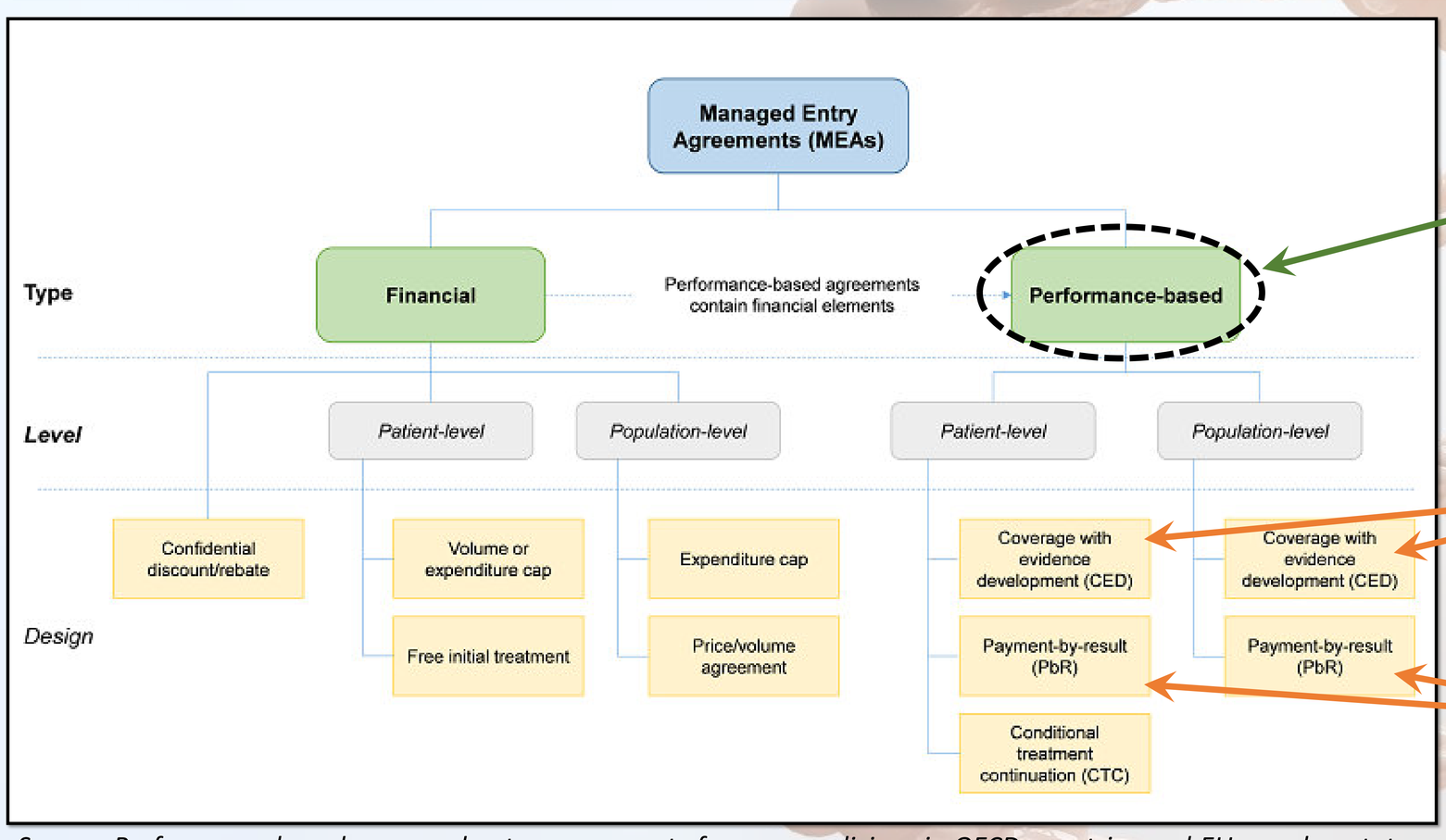
➢ 'Risk-sharing agreements / arrangements between a manufacturer and a payer to enable access to a health technology (e.g.: ATMP) subject to specified conditions

➢ Address uncertainty about the performance of an ATMP or manage ATMP adoption to maximize their effective use or limit their budget impact

➢ Used mostly for orphan disease treatments as these medicines have high prices and also uncertainties on their long-term efficacy data

Aim of the payers	Aim of the firms
To provide patient access to new ATMPs quickly and at lower prices after marketing authorization	To sell the highest volume of ATMPs at the highest price

PROBLEMS	CONSEQUENCES
High prices of ATMPs: › several years of development › high technicity › highly educated scientists › small number of patients (mostly with orphan diseases) › short period of treatment	**Limited affordability** for patients and for States
High risks: › medical uncertainty › low number of patients, the laboratories cannot test the products on enough individuals to receive the market authorisation earlier	**Delayed market entry** compared to other medicines
Heterogeneous types of ATMPs: do not fit in the current regulatory and economic framework	**Risk-based approach** for manufacturers: choosing appropriate measures for each product instead of applying Good Manufacturing Practices → higher responsibility for medicine production
Lack of transparency between Member States regarding price and efficiency of a new medicine	**Less international cooperation**, slower pharmaceutical trade
Complex fabrication and logistics of the distribution	**Geographically inequal, slower and more expensive distribution and fabrication**



Source: Performance-based managed entry agreements for new medicines in OECD countries and EU member states, https://www.oecd.org/fr/sante/systemes-sante/pharma-managed-entry-agreements.htm (last seen: 03/10/2022)

More and more countries use this type of agreement with pharmaceutical companies to make sure to pay only for a treatment that works. However, 2/3 of EU States still use financial agreements.

Coverage with evidence development: fixed prices based on evidence of clinical trials and previous patient experiences

Payment-by-result: buyer pays only after those patients on whom the therapy worked

PRESENT → FUTURE

DIFFICULTIES of the application of performance-based agreements	GOOD PRACTICES of performance-based agreements
Administrative burden to collect data	Used when benefit of **additional evidence** on product performance **outweighs the cost of** negotiating and executing other **MEAs**
Risk selection: Payment-by-Result – the therapy would be given only to those patients on whom it is 100% successful	Appropriate data sources and research designs to **address uncertainties**
High confidentiality of all parts of the contracts	**Transparency** assured by governance frameworks to allow payers to act upon additional evidences (e.g. exit or withdrawal the coverage)
Lack of transparency of MEAs' process and content	Minimum transparency level of MEAs' content and **limited confidentiality**