

# EU Pharmaceutical Law Forum

## Market Access Challenges and Developments for Pharmaceutical Firms

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# Market access challenges

- Legal nature of price and reimbursement decisions.
- Managed entry agreements.
- Deferred payment models.
- Raising costs and upward price reviews.
- Price control systems and incremental innovation.
- Transparency.
- Access to medicinal products and fundamental rights.

# Legal nature of price and reimbursement decisions

- Unilateral rulings or actual agreements.
- Agreement scenario:
  - Shared contribution.
  - Helps interaction with public system.
  - Provides value for both parties.
  - May include clauses to protect market exclusivity.
  - Amendments/reviews subject to mutual consent.
- Ruling scenario:
  - Classical administrative law approach that may be preferred by some authorities.

# Early access and managed entry agreements

- Early access programmes: free or paid for? Impact on reimbursement strategy.
- Practical aspects on implementation of managed entry schemes.
  - Info systems and decision making bodies.
  - Impact on ordinary business (i.e. unusual orders).
  - Link with patient support programmes or similar initiatives.
- Price reviews based on automatic formulas.
- Impact of life cycle management decisions.

# Deferred payment models

- The challenge of financing advanced therapies: One-time treatment may not fit the payor's (annual) budget.
- Impact of public procurement rules.
- Navigating the waters of public budgetary rules.

# Raising costs and upward price reviews

- The link between low prices and shortages.
- Regulatory actions against withdrawal of products from the market.
- EU rules and jurisprudence on prices not being an obstacle to intra-EU commerce.

# Price control systems and incremental innovation

- The concept and relevance of incremental innovation.
- Are price control systems too rigid for incremental innovation?
- Linking high unmet medical need (HUMN) for Orphan Medicinal Products (OMPs) and unmet medical needs for non-OMPs with years of protection – more or less transformative treatments?.

# Transparency

- An economic approach to transparency. What does economic theory show about the effects of price transparency?.
- Recent decisions on access to price and reimbursement rulings.
- Individual prices in tender decisions: to what extent do we need to make this transparent.



# Access to medicinal products and fundamental rights

- Recent rulings on the protection of patients via Constitutional rights.
- The right to equal treatment and how much evidence may be required from individual patients.
- The fundamental right to life as something more than the mere right to exist.

**Thank you for your attention**

