

# EU Pharmaceutical Law Forum

## Regulatory Frameworks for Healthcare Systems Solutions and Market Access Strategies

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## ■ A novel approach

- Innovation goes beyond the product and becomes part of a value proposition.
- From supply (0) to going "beyond the pill" (+1) to redefining what a company may offer to the system (+...N).
- Classic suppliers may become solution providers.

## ■ Legal challenges

- Public procurement rules.
- Competition law.
- Regulatory, compliance and transparency.

## ■ How may legal teams support this?

- We also need to move from an easy "no" to a more challenging "favor libertatis" environment.
- Ideas based on "precautionary principles" should not create excessive obstacles.

### ■ Improvements

- Offer beyond what the invitation to tender defines as minimum deliverable.
- Must be related to the subject matter of the contract and for a value substantially below the supply price.
- May only be considered in assessing offers if expressly foreseen in the invitation to tender.

### ■ Mixed contracts

- Contracting authority has a lot of freedom (discretion) to decide what it wants to purchase.
- Contract may comprise supply + works + services provided there is a functional unit.
- Value is not a limit. Basic limit is adequacy to public interests to be met via the contract.

### ■ Collaboration agreements

- Possible when there is a common objective / benefit, but subject matter cannot be the supply, and no consideration should be expected from the contracting authority.

### ■ **Competition law**

- Absent dominance, there exists a very wide space for innovative mechanisms.

### ■ **Compliance**

- Commercial activities normally fall outside the scope of application of Codes.

### ■ **Regulatory environment**

- Tendency for more sophisticated MA's and P&R rulings will do nothing but increase.

### ■ **Transparency**

- Need to find suitable balance, having the best of both worlds may not always be possible.