

Problems and solutions for implementation of risk sharing schemes in Central and Eastern European countries

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Perspective of payers in CEE countries

- Uncertain health outcomes and budget impact of innovative pharmaceutical products
- The price of new technologies is often above what is affordable or what is value based
- Potential solutions for both problems to improve patient access: risk-sharing agreements

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Necessities of implementing risk-sharing schemes

1. Knowledge: ability to judge the value of new technologies (e.g. HTA body)
2. Target: e.g. threshold
3. Legal process: willingness and opportunity to negotiate about the price
4. Real world data (claims database or patient registry): for the implementation of discount, rebate, or payback

Some of these are missing in several CEE countries

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Success criteria to implement MEAs *How to select outcome parameters for MEA?*

- Objective measure for the cost/outcome parameter (i.e. no room for manipulation)
- Payback can be monitored and audited
- Low cost of implementation (including measurement of the outcome parameter)
- Legal framework to support confidentiality (to avoid externalities)

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Legal framework: ex-ante or ex-post price discount?

- Ex-ante with published discount
 - full transparency with significant market externalities
- Ex-ante: price discount is given in advance
 - fairly easy administration
 - price discount can be calculated by different stakeholders
 - risk for externalities
- Ex-post: price discount is implemented with payback system
 - more difficult implementation
 - price discount cannot be calculated by any other stakeholders
 - limited risk for externalities

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Managed entry agreement

- Managed entry agreements =
 - risk-sharing: to reduce uncertainty of payers
 - confidentiality: to facilitate differential pricing in order to increase patient access

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Confidentiality of MEAs

- Process
 - must be highly transparent
 - preferably described in legislation
- Individual managed entry agreements
 - content should remain confidential
 - are described in legally binding documents
 - both stakeholders should remain accountable for the agreement
 - if necessary, agreements and or payback calculations can be reviewed by independent auditors

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Phases of MEA implementation

- Early phase
 - Early implementation of financial MEAs
- Medium term
 - Routine implementation of financial risk-MEAs
 - Pilot outcome based MEAs with minimal extra data collection
 - Solid legal framework
- Long term
 - Financial and outcome based MEAs
 - reconsideration of collecting additional data (i.e. minor but necessary)
 - link between patient registries and claims databases

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