Financial-based agreements and performance-based agreements: the Belgian experience

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Introduction

Managed entry agreements

Financial-based arrangements

To manage budget impact

- Patient-level schemes
  - Patient utilisation cap
  - Patient cost cap
  - Free/discounted treatment initiation

- Population-level schemes
  - Discount
  - Price-volume agreement with cap
  - Price-volume agreement without cap

Performance-based risk-sharing arrangements

To manage utilisation in the real world

- Performance linked reimbursement
  - Outcomes guarantees
  - Process of care

To provide evidence regarding decision uncertainty

- Coverage with evidence development
  - Only with research
  - Only in research

Access for all indicated patients

Adapted from Garrison et al. (2013) – ISPOR taxonomy
Legal framework in Belgium

Royal Decree 21 December 2001

Therapeutic value
- Safety
- Efficacy
- Effectiveness
- Applicability and convenience

Price
Medical and social need
Budget impact
Cost-benefit ratio

Class 1
Orphan drug
Positive

Class 2
Negative
No advice

Class 3

Since July 1st 2014
Objective & methodology

The aim of this study was to investigate the experience of different stakeholders with managed entry agreements in Belgium.

- Semi-structured interviews were conducted between September and December 2014
- Interviewees were recruited through purposive sampling
- Interviews were audio-recorded, verbatim transcribed and analyzed using the grounded theory approach.
Results

7 representatives of a pharmaceutical company or industry association

*Further indicated as industry (I)*

3 representatives of NIHDI
3 representatives of sickness funds

*Further indicated as payer (P)*

3 health care providers

*Further indicated as clinicians (C)*
Advantages

“The patients do have access to the medicines, otherwise it would have been a “no”” (I1)

“Without these agreements, a number of products would not reach the market” (P1)

“The most important thing is that it makes the medicines available to the patient” (C1)
Advantages

- Access to the treatment for patients
- Flexibility
- More room for negotiation
- Allows generation of real-world evidence
- Engagements are clearly stipulated in a contract
Disadvantages

• Extends time to the market
• Workload
• Hard to withdraw product from the market after agreement
• Period of agreement is insufficient to start new studies
• Comprehensive clauses are necessary
Disadvantages

“These agreements can not be the standard for access to innovation” (I2)

“At the moment that these agreements were introduced in the law, it was aimed to apply it in exceptional cases. The current practice is completely different: it is applied in almost every case” (I3)
Financial-based agreements

“There is no performance-based agreement today...or maybe there is one...but with serious financial deals” (I3)

“Price/volume agreements are definitely the majority...The question for additional data comes off second-best” (P2)

“In general it are financial-based agreements, in combination with additional evidence generation” (P3)
Financial-based agreements: drivers

“The advantage compared to a classical subscription is that there is a flexible manner to find a solution, a financial solution in general, to address uncertainties.

....
And at the same time there is a financial security.

...
Another benefit is that you get the product in real-life practice and start collecting evidence in practice, without financial risks.” (P3)
Financial-based agreements: drivers

Lack of trust by payer in company and rationale behind price setting

“Why do companies set such prices for their products? If they would ask reasonable prices, we would not need those contracts.” (P4)

“They want more than what the products delivers as added value” (P2)
Financial-based agreements: drivers

Lack of trust by company in payer and rationale behind decisions

“One of the current difficulties is that the conventional working party is too much driven by budget...not to say dominantly driven by budget.” (I5)

“What they call risk-sharing now, it not real risk-sharing, but protection of the budget of payers” (I3)
Financial-based agreements: drivers

External reference price setting (ERP)

“These purely financial agreements are good to get the product on the market without affecting the whole European context…” (I1)

“An advantage, and the reason why all this has been effected, is that it allows a high list price compared to the net cost for the NIHDI” (I3)
Financial-based agreements: drivers

- Lack of trust by payer in company and rationale behind price setting
- No concession in price
- ERP
- Application article 81
- Lack of trust by company in payer and rationale behind decisions
Performance-based agreements

“*It would be better if we can use more performance-based risk-sharing agreements instead of purely financial agreements*” (I5)

“Data collection *can be positive for a company*, we better understand our market...For an indication were there are only 40-50 patients, it is perfectly feasible” (I2)

“I think companies would like to go in the direction of performance-based agreements, but its an unknown field, we do not have years of experience in that” (I1)
Performance-based agreements

“I think that in certain cases, performance-based agreements are interesting... The company pays for drugs that are not successful, and that the government pays if there was a success. I think it is perfectly justifiable.” (P1)

“Pharmacists will be involved in data-sharing, but it will be a step-by-step evolution.” (C1)
Performance-based agreements: hurdles

- Additional workload
- Complex
- Need for registers
- Need for data-sharing

“Additional workload, registers, individual follow-up...I think that also pushed the application of financial-based agreements instead of performance-based agreements” (P5)

- Duration of contracts is not sufficient to start new studies
Current evolutions

- **Belgium**
  - Future pact from Minister of Health and Social affairs
    - More focus on performance-based agreements

- **European level**
  - Products will enter the market earlier
    - Adaptive pathways
    - Early temporary authorization/reimbursement
Conclusions

• Cost-saving measures (including ERP) drive application of financial-based agreements

• Application of financial-based agreements counters cost-saving measures (including ERP)

• Need for more focus on value of the drug by all stakeholders

• Current evolutions require a move towards performance-based agreements
Questions?