



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

Kim Pauwels

Promotor: Prof. Steven Simoens

Co-promotor: Prof. Isabelle Huys, Prof. Minne  
Casteels



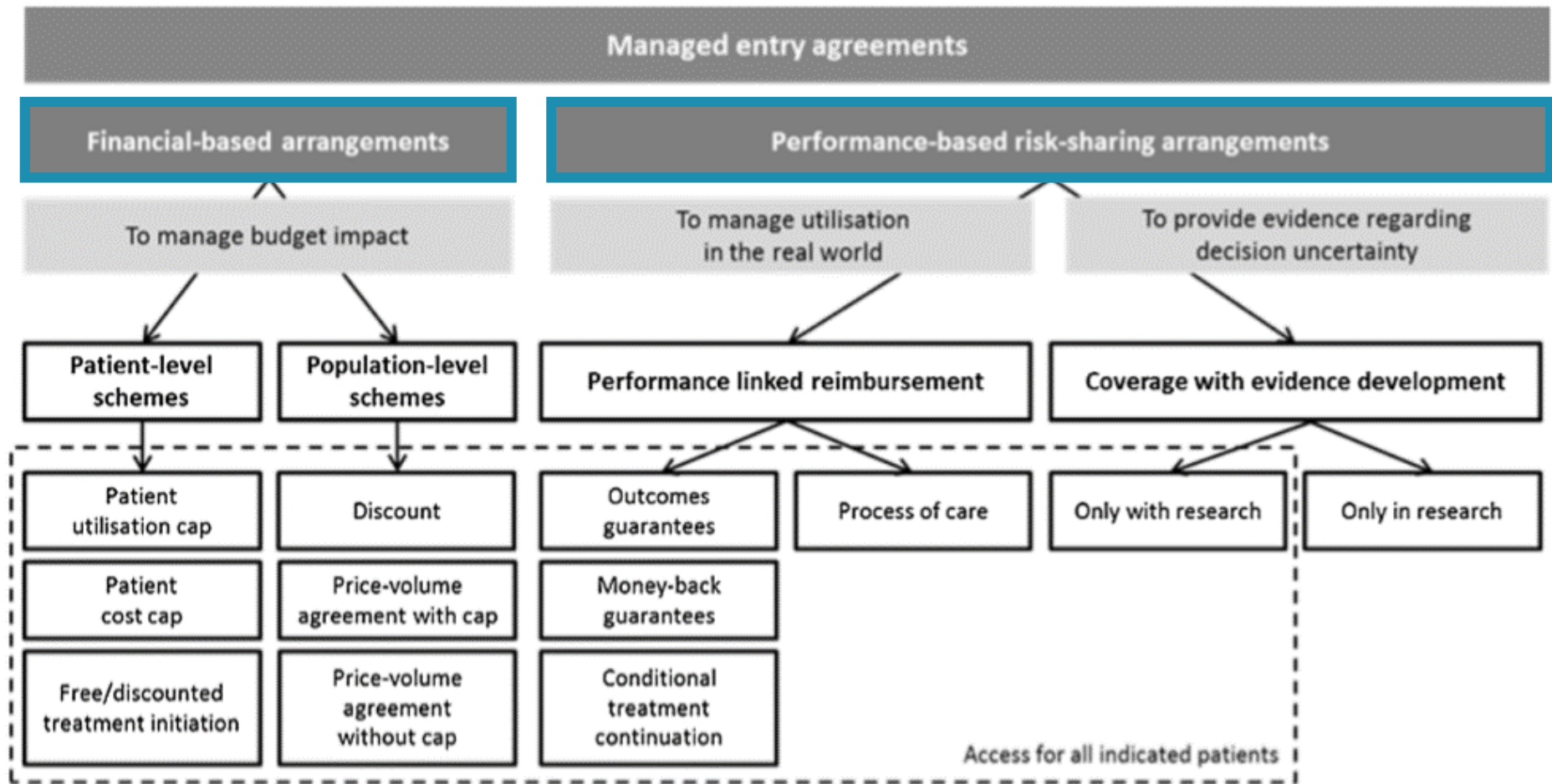
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# Outline

- Introduction
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- Results & discussion
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# Introduction



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

Class 2

Class 3

Positive

Negative

No advice

Article 81

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.” (15)*

*“What they call risk-sharing now, it not real risk-sharing, but protection of the **budget** of payers” (13)*



# Financial-based agreements: drivers

## External reference price setting (ERP)

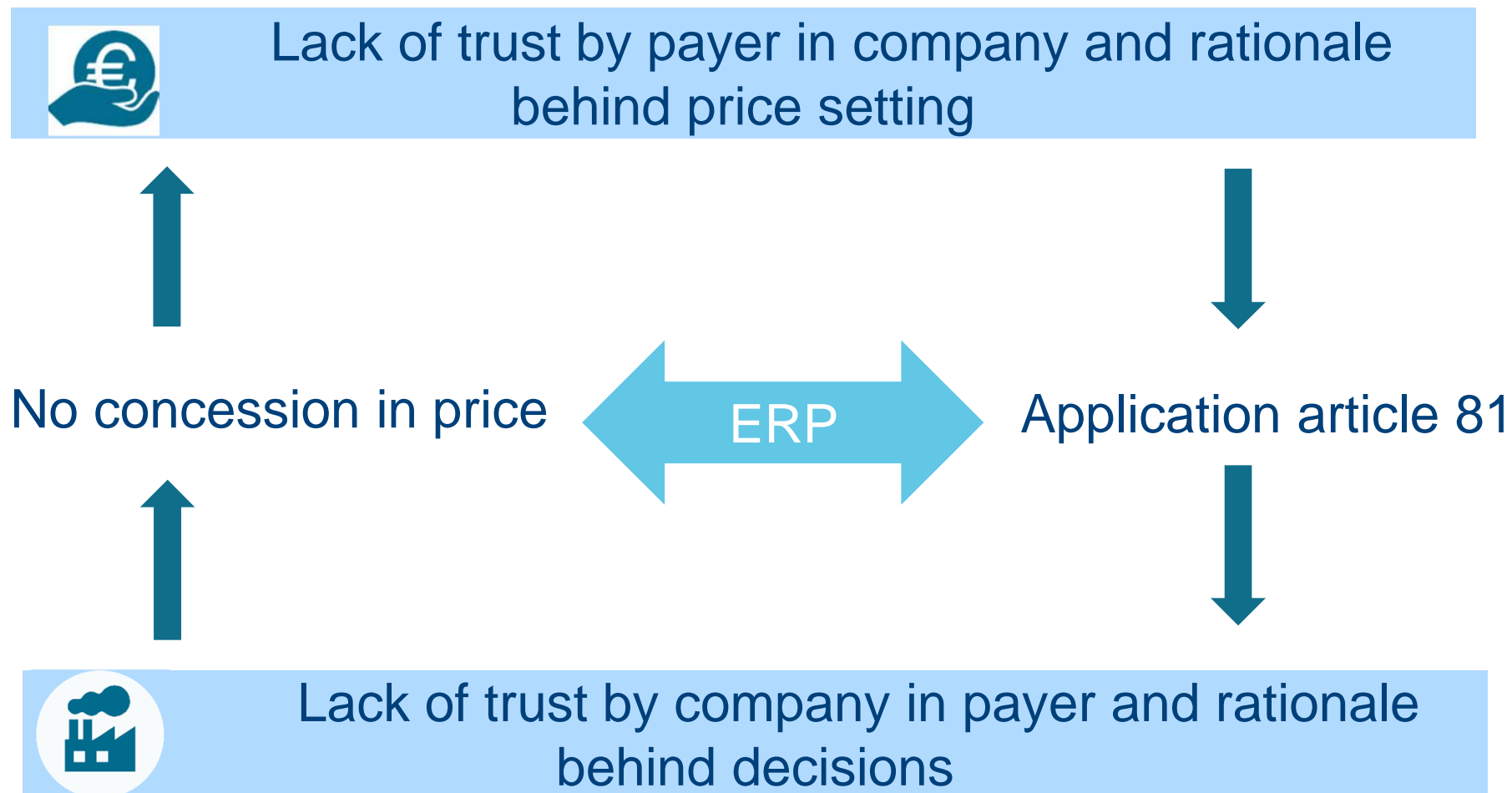
*“These purely financial agreements are good to get the product on the market **without affecting the whole european context...**” (I1)*

*“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



# 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 where 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 it's 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?

