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Real life evidence generation and performance based reimbursement – First experimenting steps in Hungary

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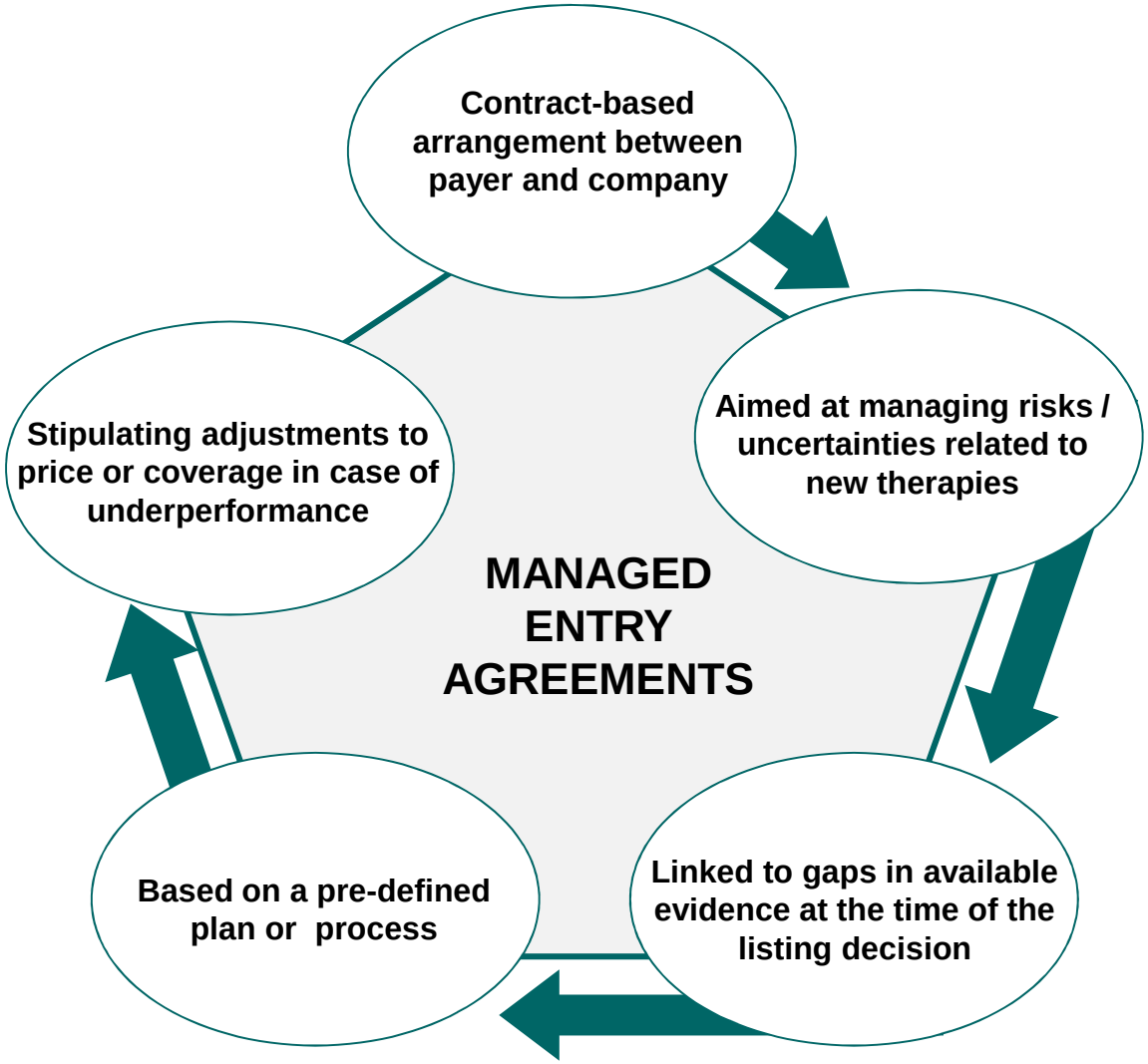
Starting point: Despite the high number of different MEA/RSS definitions, there are marked common elements across them

Ferrario A. – Kanavos P. (2013)
EMINET

„[MEA's are] formal arrangements between payers and manufacturers with the aim of sharing the (…) risk due to uncertainty surrounding the introduction of new technologies (…) in order to enable access to new medicines."

Garrison et al. (2013)
ISPOR

„Performance-based risk-sharing arrangements" (PBRSA's) involve a plan by which the performance of the product is tracked in a defined patient population over a specified period of time and the level or continuation of reimbursement is based on the health and economic outcomes achieved."

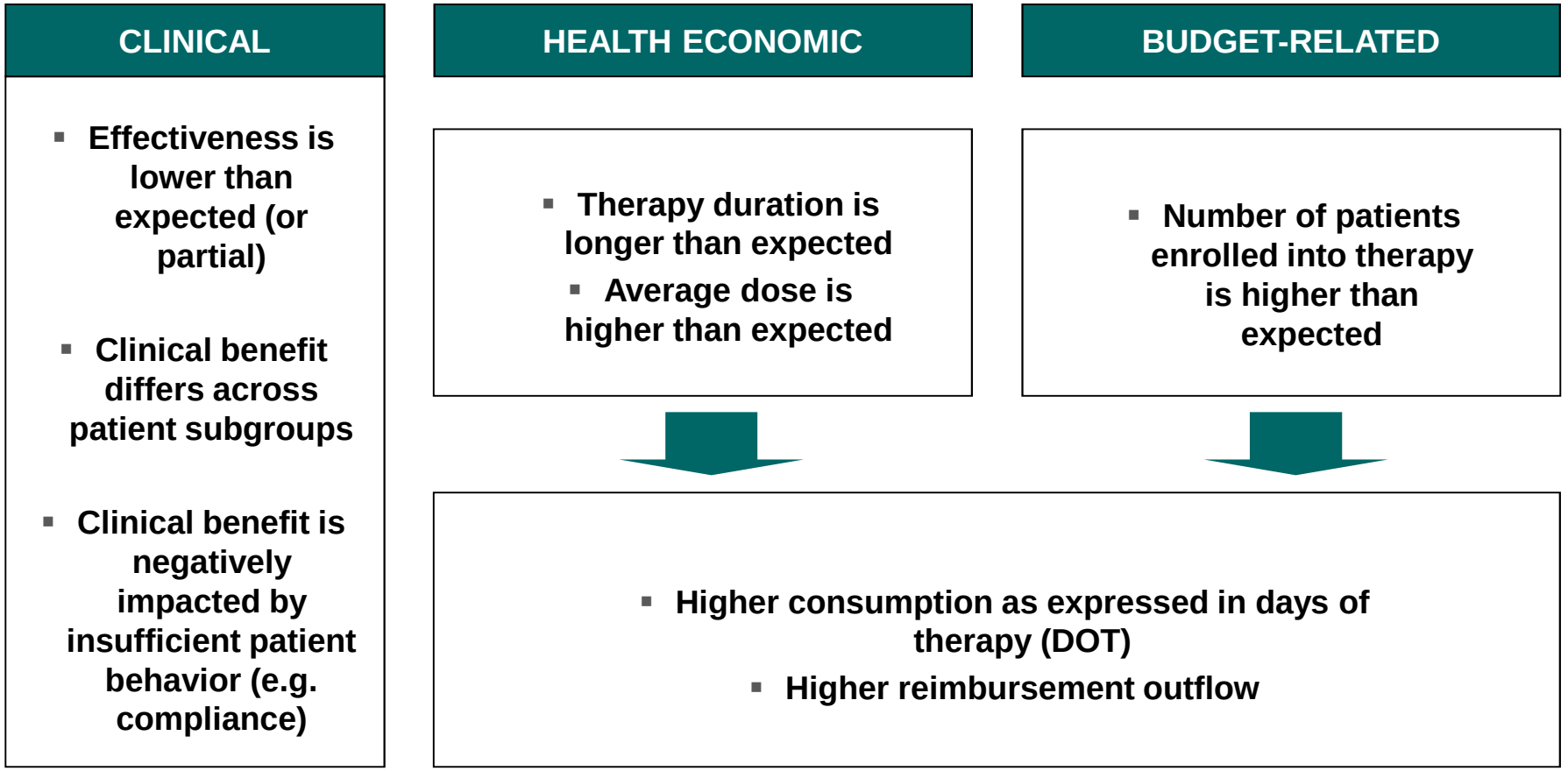


Different characteristics of cost-sharing, risk-sharing and affordability schemes

	Cost-sharing schemes	Risk-sharing schemes	Affordability schemes
Mitigation of total budget impact over product lifecycle	YES, by definition	YES, in function of product performance	NO
Deferred payment between financial periods	NO	NO	YES
Mitigation of clinical uncertainties related to new therapy	NO	YES	NO
Mitigation of economic uncertainties related to new therapy	NO	YES	NO

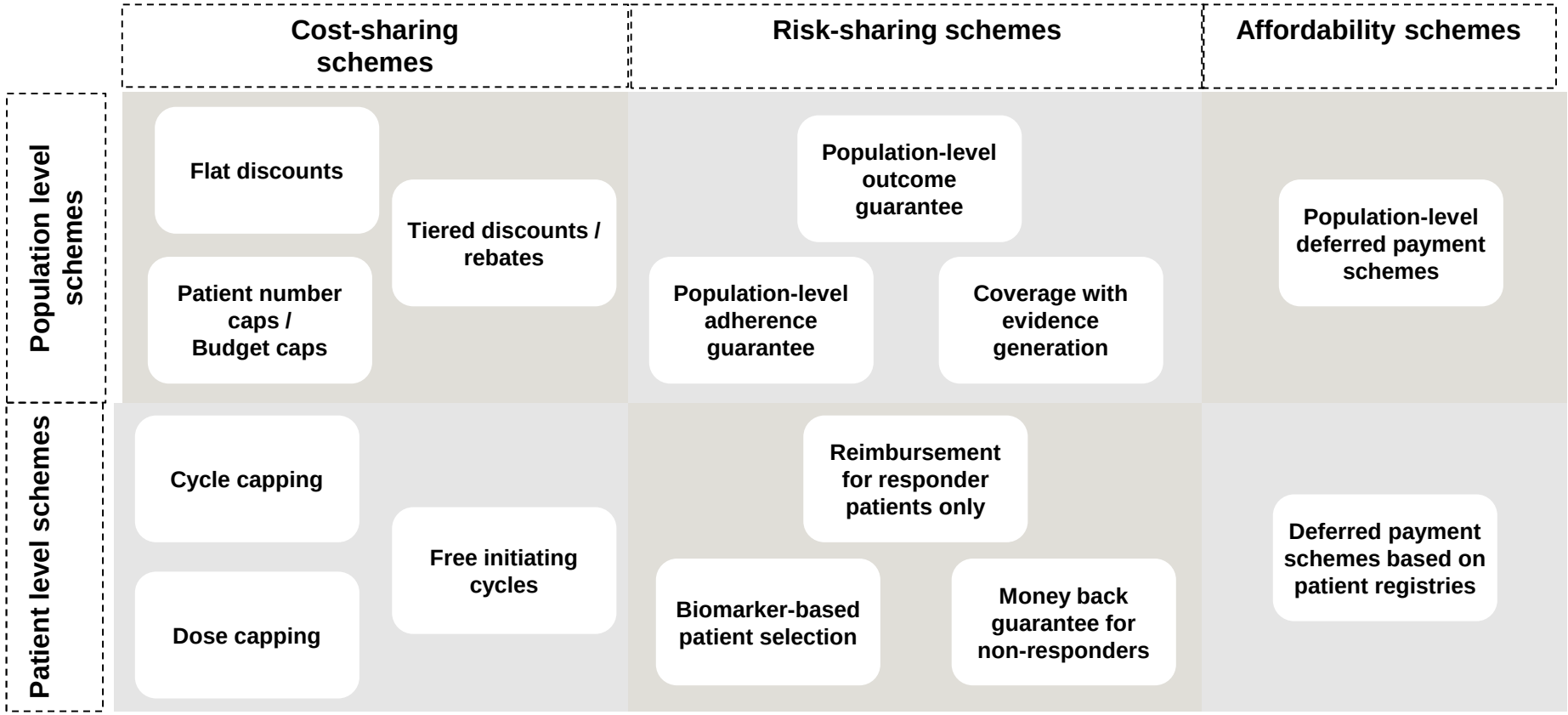
If there is no risk to be shared, there is no risk-sharing scheme.

Risk-sharing: some major uncertainties related to new medicinal therapies from the payer's perspective



Risk-sharing schemes can often address more types of interrelated uncertainties.

For everyday use, a simple matrix typology may be sufficient



At least in theory, in Hungary you can find most of the categories above.

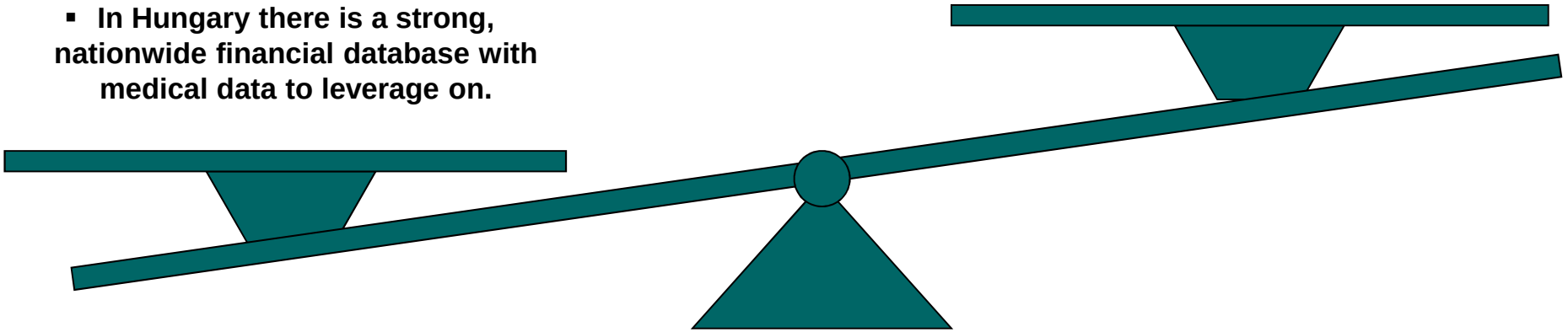
Does Hungary matter on the global map of MEAs?

Yes…

- Hungary was among the first countries to investigate the opportunities for MEAs back in 2006, and to establish legal background for MEAs.
- The payers in Hungary are interested in MEAs from scientific and institutional perspective as well.
- In Hungary there is a strong, nationwide financial database with medical data to leverage on.

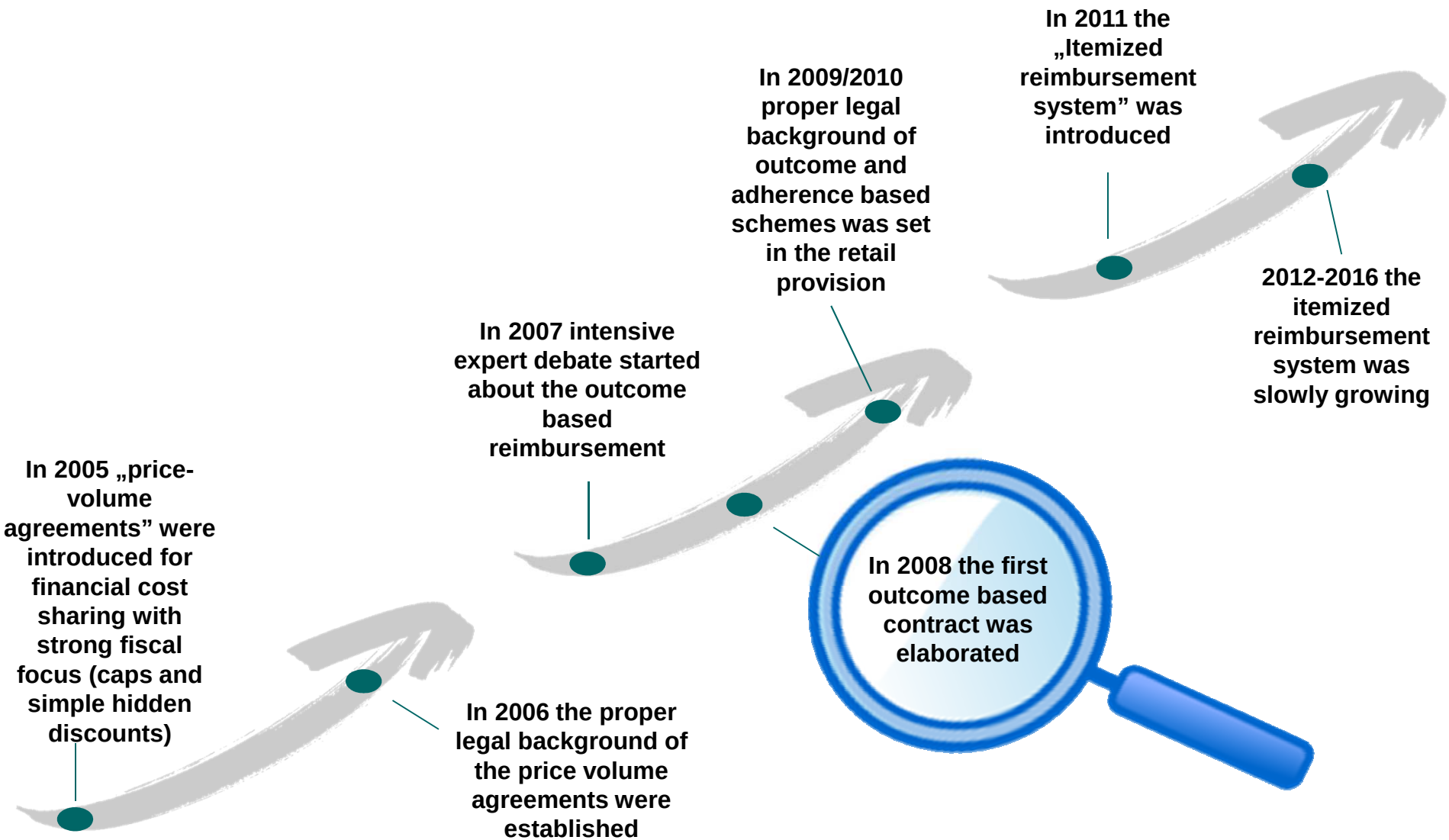
No…

- Hungary is a below-the-line pharma market at global level, and therefore it is not always easy to adapt the experiences in a different context.



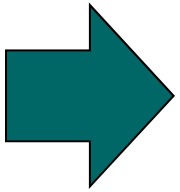
Hungary might not be very significant with global measures, but this fact with several supporting factors may qualify the country to be the test field of innovative solutions for pharma companies, that later on can be implemented on larger markets, and Hungary might be also a learning field for other countries trying to implement MEAs.

Implementation of MEAs in Hungary



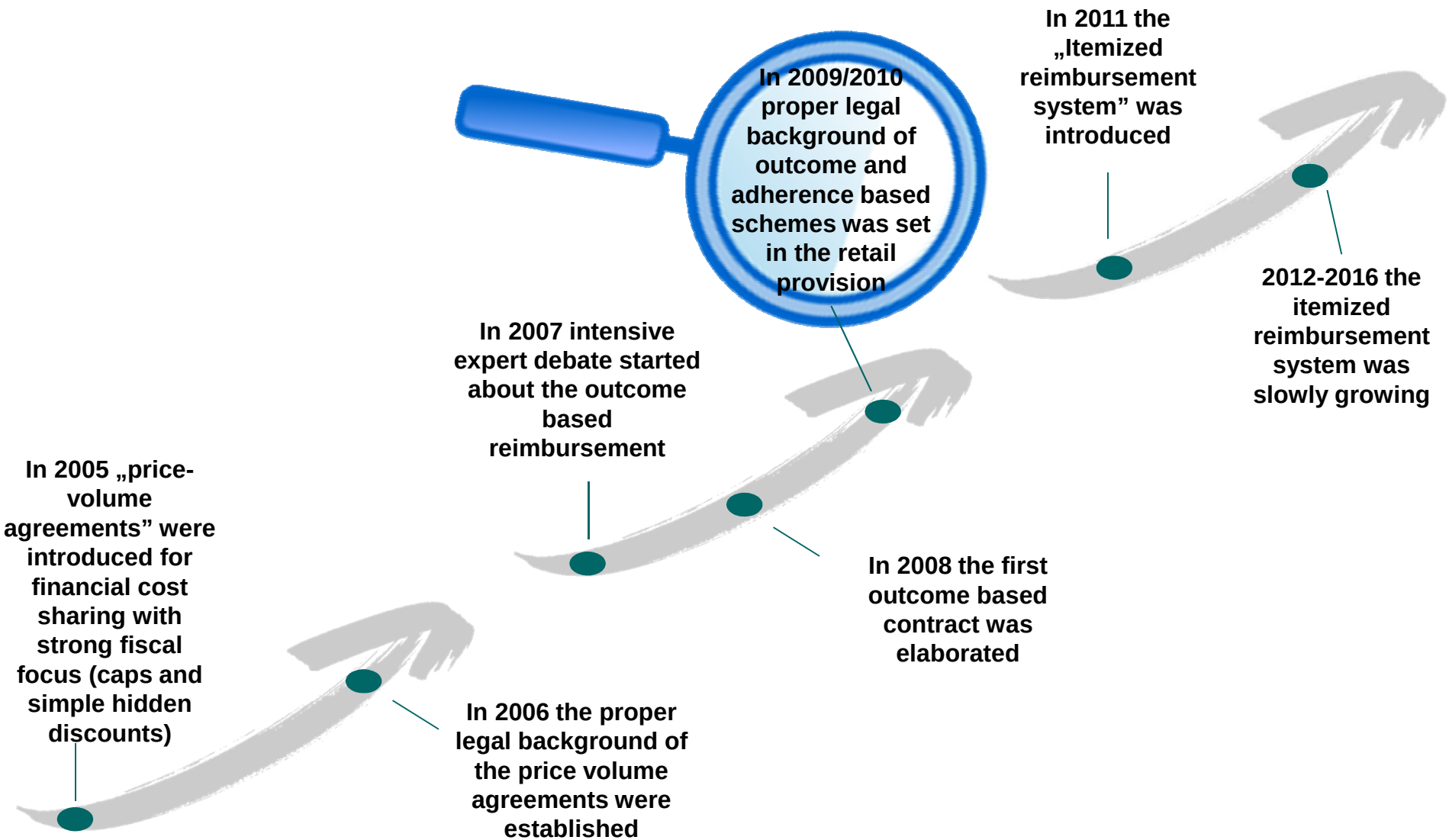
First outcome based agreement – 2008/2009

- After an intensive period of public – or rather expert talk – the sick fund prepared the first performance based scheme in the retail budget
- Its type was population level outcome guarantee
- The major motivation from the sick fund side was cost control or cost saving rather than conceptual clarity
- The basis of measurement was the financial database without primary data collection
- The new wave of oral anticoagulants accepted to pay back the real and total cost of bleeding episodes or thrombosis, in case of exceeding the rates in the studies.



After a long waiting for the listing decision, these manufacturers offered in 2010 to the sick fund a very simple and large enough discount, so the scheme was never implemented.

Implementation of MEAs in Hungary



Legislation background in Hungary related to MEAs

Cost / risk sharing is mandatory for all new INNs and indications

The duration of agreements may be max. 4 calendar years

For contracts covering a period longer than a year, an obligatory advance payment may be required by NHIF

In every year, the payer revises the list of publicly reimbursed pharmaceuticals to assess the possibility of contracting

Price-volume agreements may be applied also for new or already listed medical devices

PAYMENT OBLIGATION MAY BE DEFINED:

- **Based on the number of reimbursed units sold (simple discounts)**
- **Based on the volume of reimbursement outflow (budget caps)**
- **Based on the estimated additional costs caused by insufficient therapeutic outcome (outcome-based agreements)**
- **Based on adherence criteria specified in the contract (adherence-based agreements)**
- **By evaluating if real life usage deviates from recommended dosage regimen**

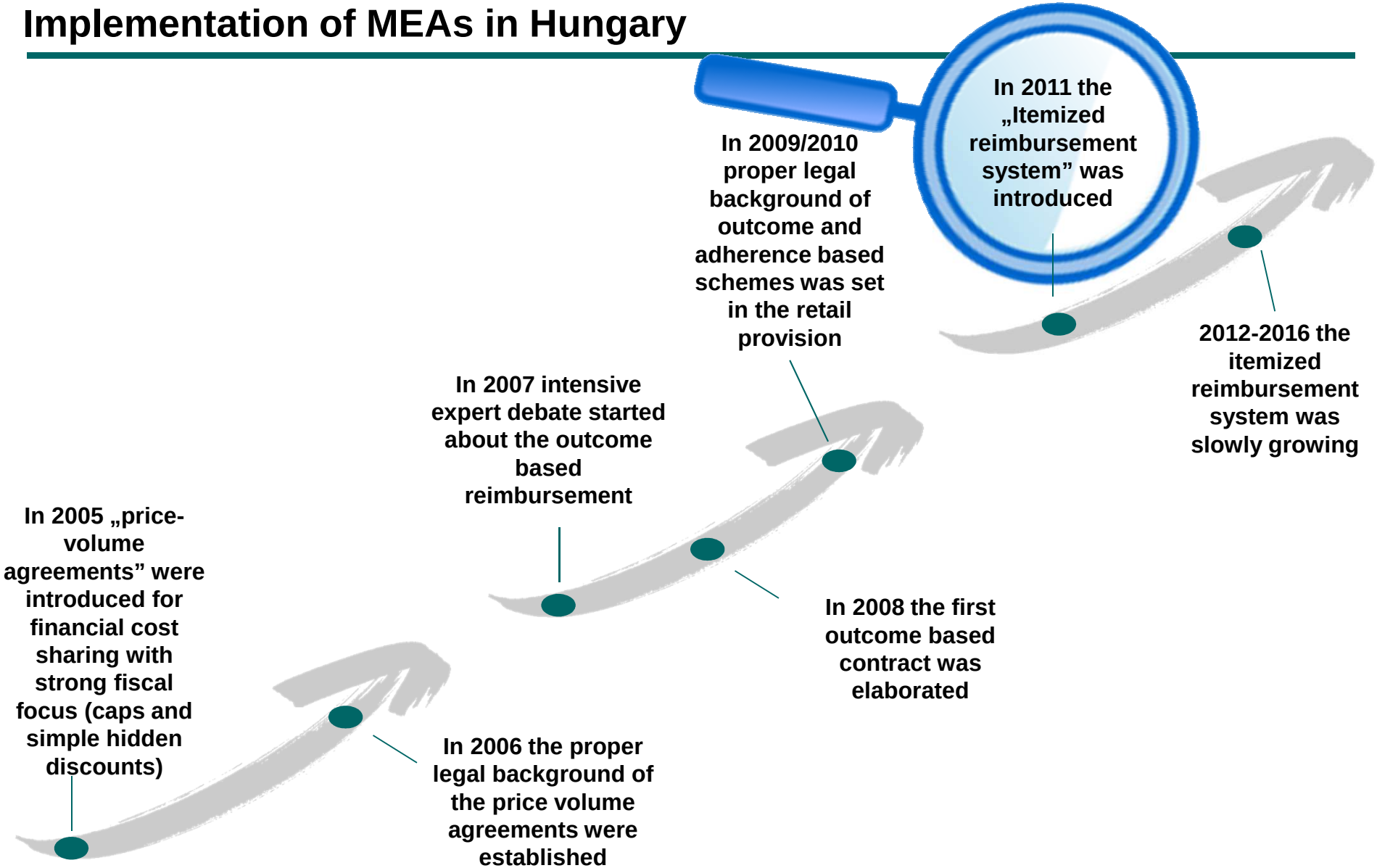
Or the combination of any of the elements.

Applied MEA types in the retail segment (contracts in force)

	Number of brands in rebate contracts	Number of brands affected by some kind of contractual cap	Number of brands with outcome-based agreements	Number of brands with combined contracts
Pharmaceuticals	54	43	2	23
Medical devices & other	0	17	0	0
Total	54	60	2	23

MEAs are quite widespread in Hungary, covering more than 120 pharmaceutical brands in the retail segment. Budget agreements have been dominant in the recent years, outcome based elements are rather loosing significance.

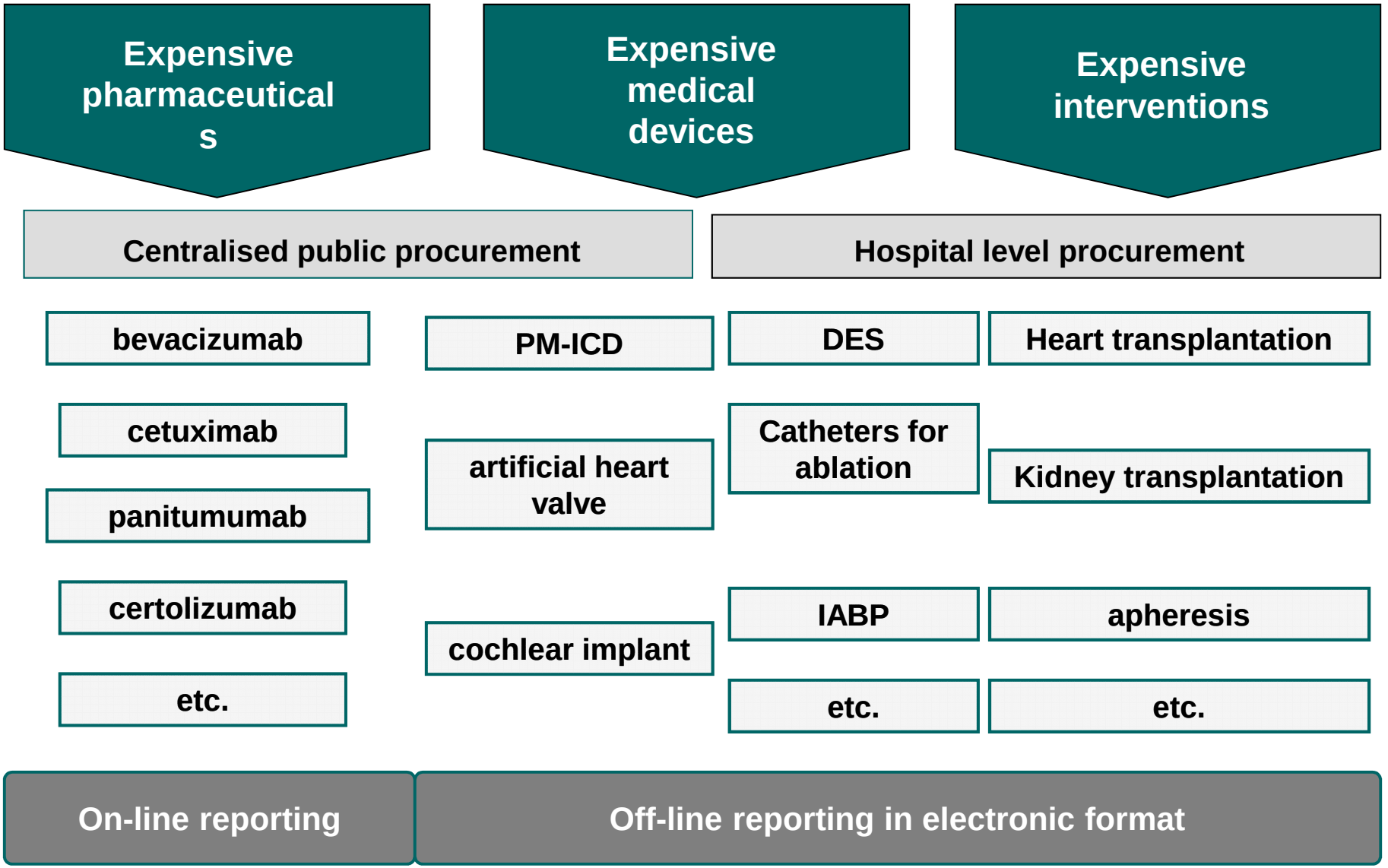
Implementation of MEAs in Hungary



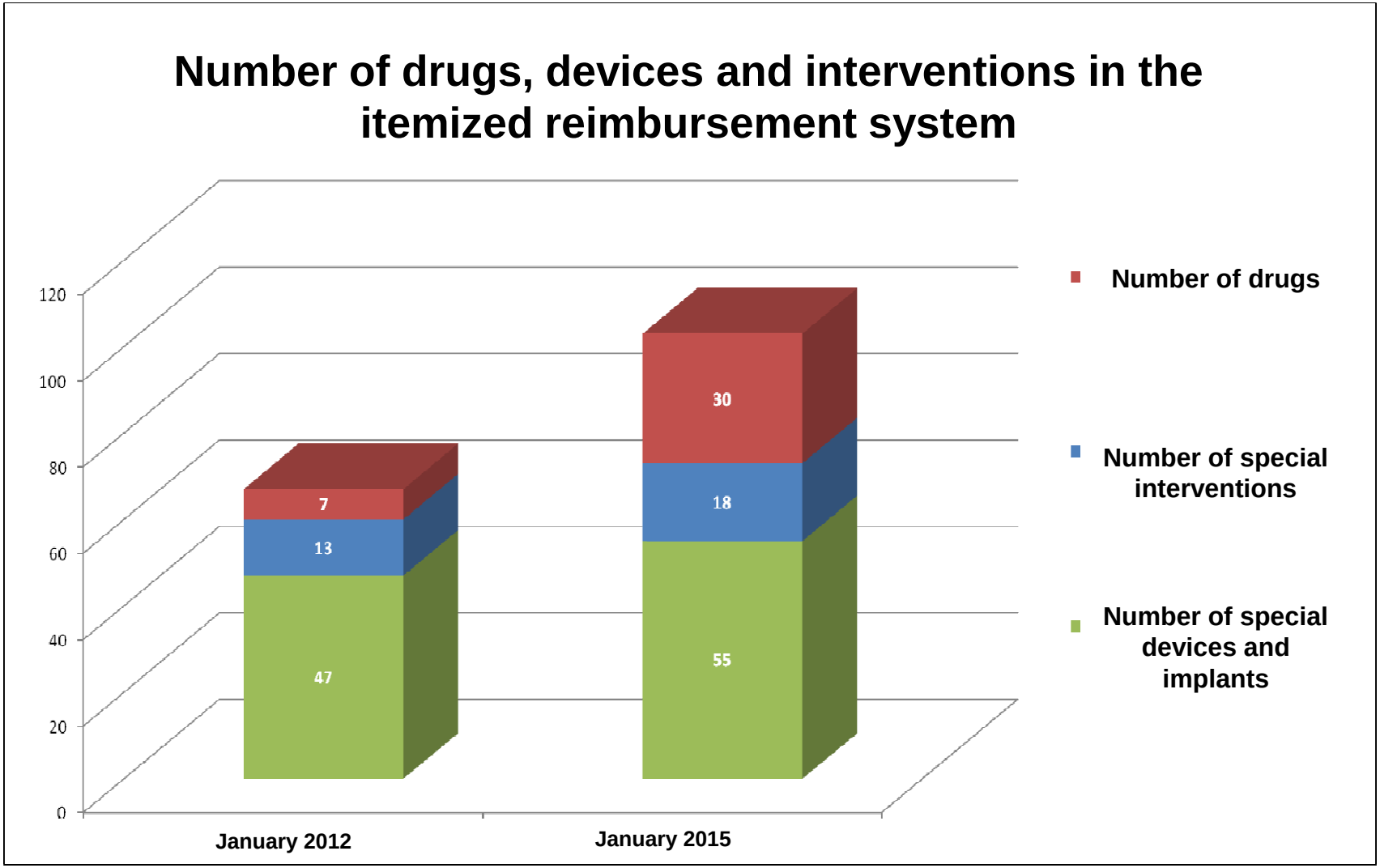
Itemized reimbursement system or special financing

Primary motivation	In 2010 Hungary faced with several instructions from the IMF. One of these was to cut the pharma budget by roughly 1/3. The plan was not manageable, so government decided to set up a new budget and hide there cc. 1/5 of the total drug expenditure. This was the itemized reimbursement system.
Secondary motivation	Though the IMF instruction was the main reason on macropolitical level, experts at the sick fund tried to give meaning of the initiative, and started to build up a registry-based reimbursement subsystem.
Key idea	They set up a separated budget for expensive products, that can be procured (preferably based on real life performance), and delivered to the patients based on the physician's report in a registry.
Technical tool	The sick fund developed on its own an IT platform, that interlinks the wholesaler, the hospital and the payer. This system is used to order products, to settle the payment, to report the delivery and to report the consumption.

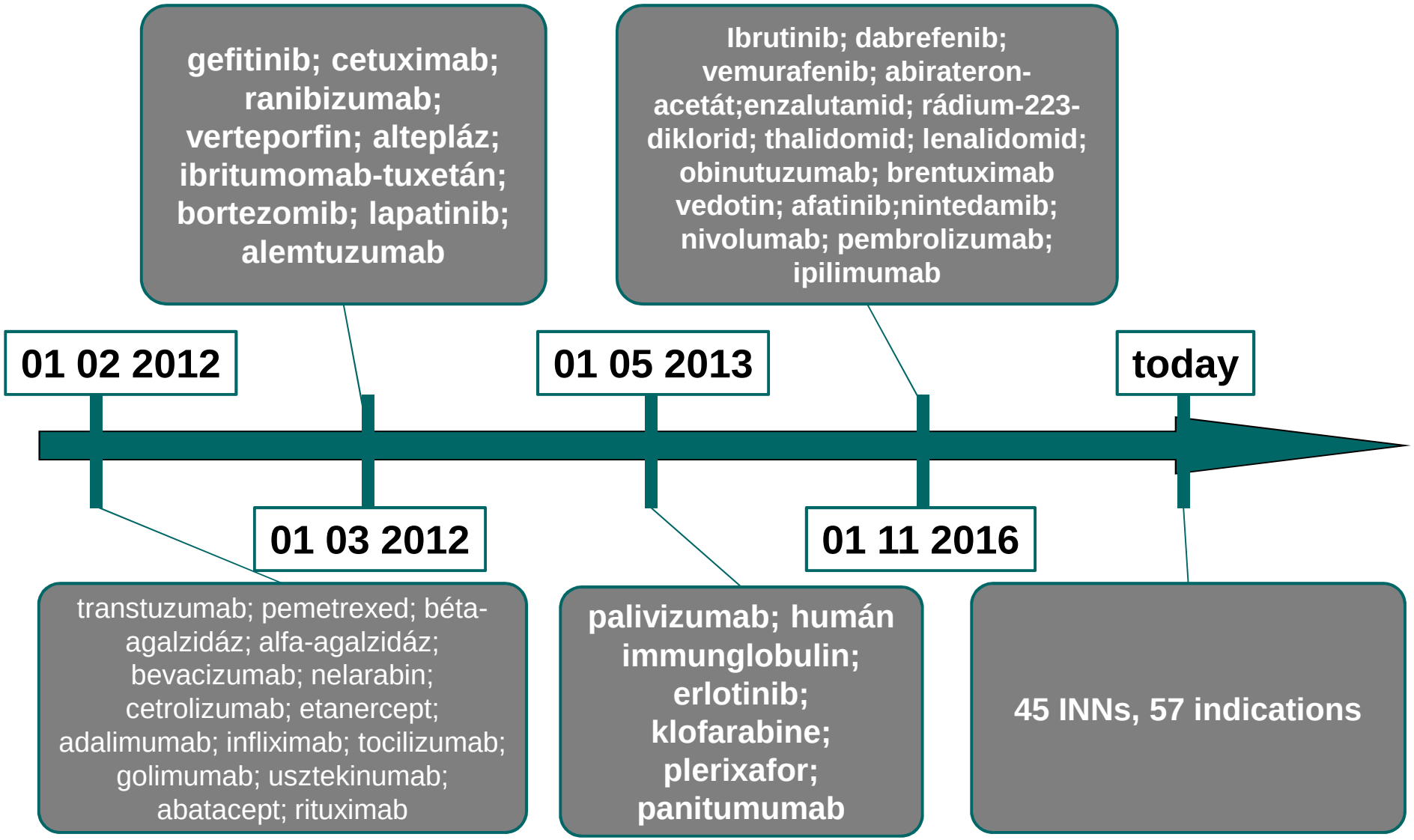
Products and services in the itemized reimbursement system



Evolution of itemized reimbursement system



Evolution milestones of the itemized reimbursement system



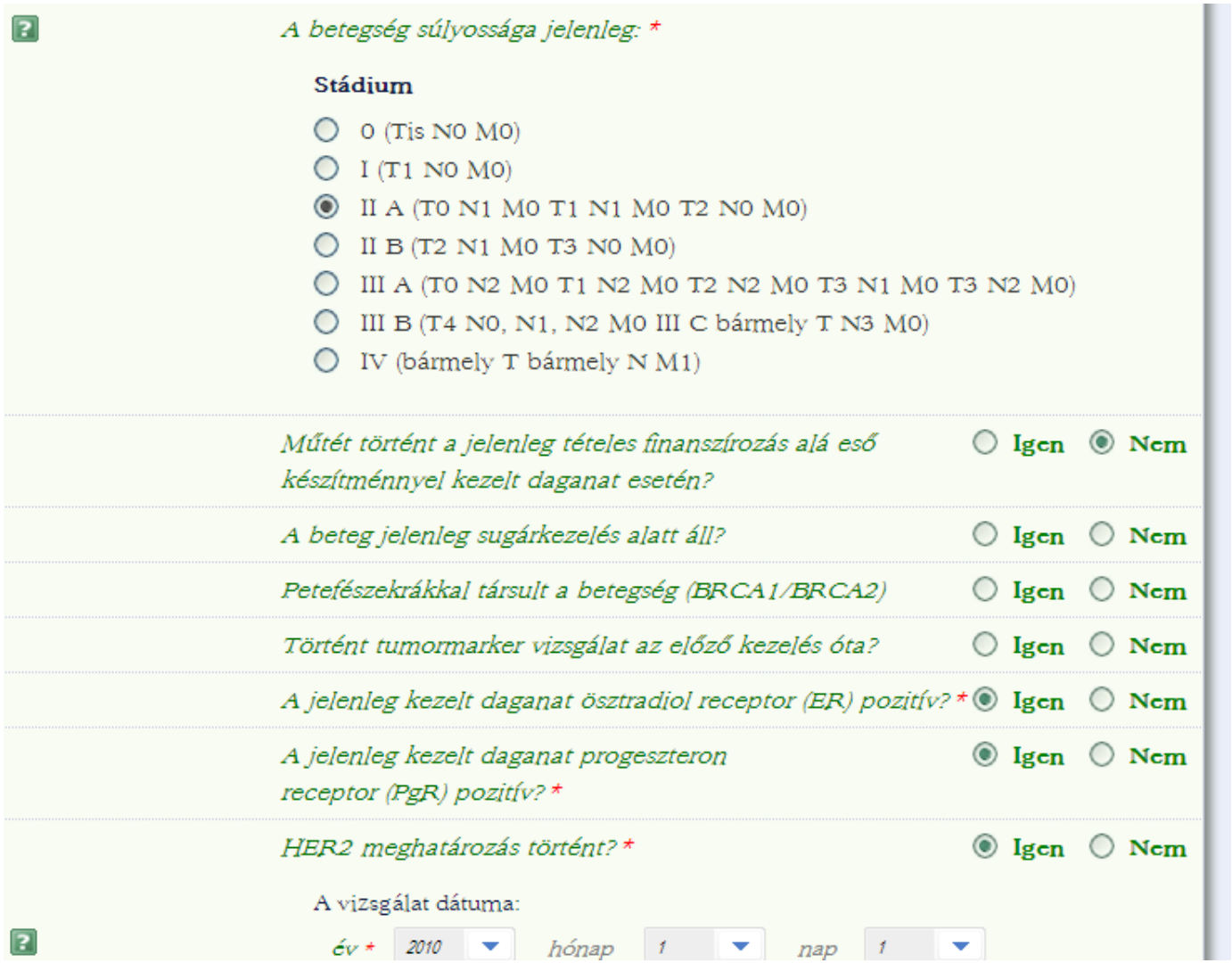
Stakeholders connected to the system up to now
Itemized reimbursement system in numbers

Physicians	2823
Pharmacists	217
Controling	102
Supervisors	115
OEP admins	10
Wholesalers	8

Patient records	475 000 db
Number of patients	50 447 fő

In terms of describing numbers, the Hungarian experience is quite significant.

How does it look like?



*A betegség súlyossága jelenleg: **

Stádium

- 0 (Tis N0 M0)
- I (T1 N0 M0)
- II A (T0 N1 M0 T1 N1 M0 T2 N0 M0)
- II B (T2 N1 M0 T3 N0 M0)
- III A (T0 N2 M0 T1 N2 M0 T2 N2 M0 T3 N1 M0 T3 N2 M0)
- III B (T4 N0, N1, N2 M0 III C bármely T N3 M0)
- IV (bármely T bármely N M1)

Műtét történt a jelenleg tételes finanszírozás alá eső készítménnyel kezelt daganat esetén?	Igen	**Nem**
A beteg jelenleg sugárkezelés alatt áll?	Igen	Nem
Petefészekrákkal társult a betegség (BRCA1/BRCA2)	Igen	Nem
Történt tumormarker vizsgálat az előző kezelés óta?	Igen	Nem
*A jelenleg kezelt daganat ösztradiol receptor (ER) pozitív? **	Igen	Nem
*A jelenleg kezelt daganat progeszteron receptor (PgR) pozitív? **	Igen	Nem
*HER2 meghatározás történt? **	Igen	Nem

A vizsgálat dátuma:

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Pros & cons of the itemized reimbursement system

- Sick fund was able to control the consumption of these molecules in a more efficient way (volume control due to the institutional quotas)
- With small niche therapy areas with very limited patient number, very limited number of physicians and very good direct link to the prescribers, the system works well, the evidence generated is fully accurate and useable even for scientific purposes (IvIg, AMD injections, thrombolysis)
- Due to the tender framework it is fully intransparent, which allows pharmaceutical companies to offer quite flexible net price discounts, and free goods, which is not possible in the retail budget
- It fully served the primary aim, IMF accepted the switch as a saving.

- Huge administrative burden for every stakeholder
- Major risk of IT breakdowns
- With larger therapy areas with more patients and more prescribers, where the sick fund does not have direct contact towards the prescribers, but only towards the medical associations, the reported data is not accurate, not useful for scientific purposes (oncology, immunology, etc).
- It was even hardly possible to achieve any major economic savings
- It is fully intransparent, the consumption data and the net cost is unknown for the public, so there is no public control on the procedures

Key learnings, conclusions

- **In therapy areas with low patient number (ultra orphans) a similar system to the Hungarian itemized reimbursement system might be implemented with high likelihood of success.**
- **To build up a personalized and robust IT system for linking the stakeholders, and to provide platform for communication, reporting and finance does not seem to be feasible. An off-the-self IT product with support might be more reasonable.**
- **Some complicated performance based systems are developed only to target financial savings, which is not rational. The implementation costs might be much more than the savings the system would bring.**
- **The purpose of using data for science is not a legit primary purpose alone, it might be only a side-effect or collateral benefit of building up an outcome based reimbursement system.**