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Drug Pricing models (MEAs) – Curse or Blessing?

This newsletter looks at whether drug pricing models or Managed Entry Agreements (MEAs) are beneficial to improve patient access and value for money, or just a new method to determine price and reimbursement?

Where it started – initial purpose

New pricing models (MEAs) are agreements between pharmaceutical companies and decision-makers and payers to accelerate the availability of promising, innovative drugs in the context of medical and economic uncertainty. MEAs reduce the consequences of a poor reimbursement decision under uncertainty. Such agreements can focus on finances or treatment outcomes to reduce payer's risks. The original idea was for the manufacturer to offer a temporary discount to make a drug more cost-effective until missing data and evidence is available (CED – Coverage with Evidence Development). However, the CED approach has so far failed to reduce uncertainty; instead conditional and temporary reimbursement are used (cf [1], [2]). Today, confidential price-volume agreements are the most common MEAs with discounts versus list prices of 20-29% [3].

"In principle, MEAs should reduce the CE-ratio for reimbursement until the medical and economic uncertainties are reduced to the usual extent by additional data"

The old conventional way for P&R versus the new MEA way

More and more, MEAs are used not only for the management of P&R of innovative drugs with a high degree of medical and economic uncertainty, but also for any new high-cost therapy. For such a cost-intensive therapy, a confidential financial discount on the list price is granted to enable differentiated pricing according to purchasing power and willingness to pay. Such an approach could become the new normal.

"Negotiations for confidential rebates are becoming just as important as medical and economic assessments in order to achieve a fair price-performance ratio."

Table 1 outlines the key differences between the old and the new pricing & reimbursement process. Consequently, negotiation is become as important as medical and economic assessment to achieve fair value for money.

Table 1: Conventional Pricing vs MEAs

Topic	Conventional P&R	MEAs (Pricing Models)	Remark
Number of listed drugs	Majority	Low single digit number	High MEA percentage of new drugs
Number of patients	Large	Orphan or Ultra Orphan	
Evidence	RCT with endpoints	Clinical-& economic uncertainty	MEAs data gaps should be addressed by CED
Treatment costs	Low to moderate	High to extremely high	
Price	ERP dependent	Confidential net price	Higher prices with confidential net prices [4]
ERP	ERP is suitable	Lack of transparency hinders ERP application	ERP Re-evaluation: price is declining over time [5]
Differential Pricing	Limited by parallel trade	According to GDP and Willingness to pay	Increase access in low- and middle-income countries
Managing Budget Impact	Fix prices frequently independent of volume	Adaptive pricing incl. price/volume agreement	MEAs can manage Budget Impact more flexible

Pros and Cons of pricing models (MEAs)

Whether MEA pricing models are beneficial for the healthcare system is controversial. Figure 1 lists the advantages and disadvantages of pricing models from pharmaLevers' point of view, whereby the individual factors were subjectively weighted as weak, medium, and strong. Accuracy and completeness are not claimed. The purpose is to start a discussion about the overall benefits of pricing models; any comment is welcome. Finally, the advantages and disadvantages of pricing models are balanced from pharmaLevers' point of view. In such a case, the benefits of earlier market access for patients become crucial. Earlier market access can be further improved by reducing the long negotiation time that is feasible when negotiations are already starting in parallel with the regulatory approval process. The biggest disadvantage of pricing models is their administrative burden, which requires a lot of additional resources. Increasing digitalization can probably improve this situation.

"The advantages and disadvantages of pricing models are balanced – so earlier market access for patients is crucial. Reducing negotiation time and digitising to reduce administrative burdens will further improve the pro-contra ratio."

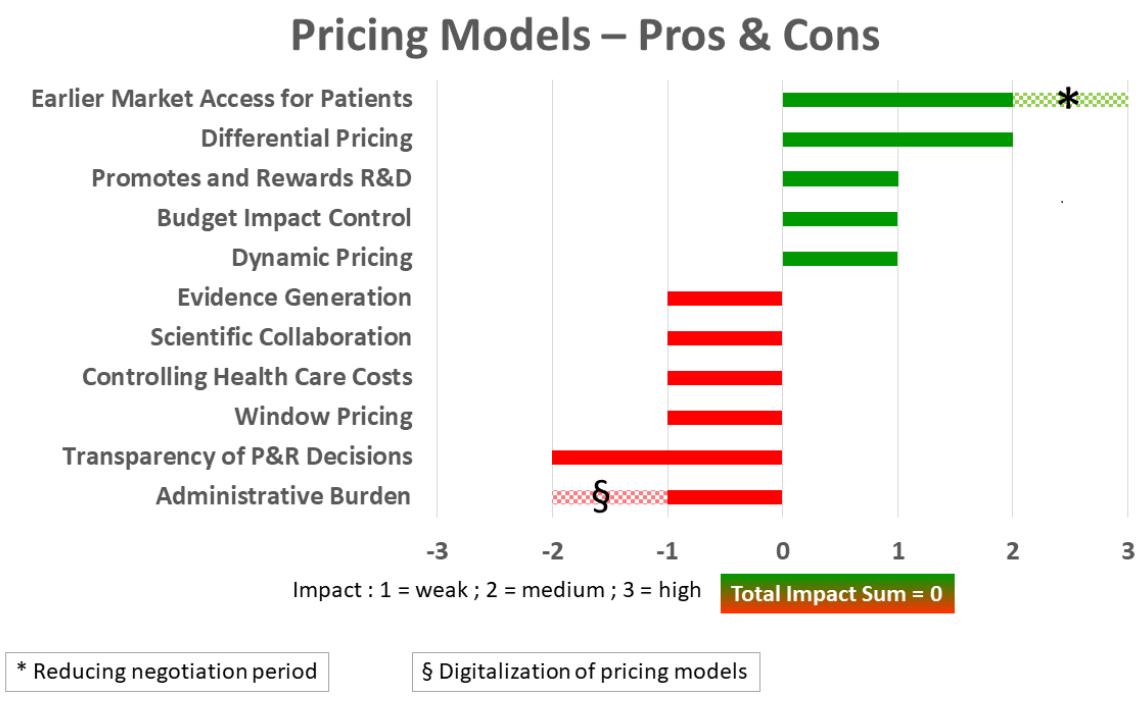

Figure 1: Pros and Cons of Pricing Models

Earlier Market Access
Enables the early reimbursement of innovations with a high medical need despite limited data and uncertainty.

Differential Pricing
Enables purchasing power-adjusted pricing in low- and middle-income countries, improving market access in these countries. This is contrast to the current situation, where the regional exhaustion of patents allows the free movement of goods which hinders country-specific prices.

Promotes & Rewards R&D
Pharmaceutical companies can generate earlier revenue through MEAs for innovation, making R&D investments more attractive.

Budget Impact Control
Budget impact uncertainties can be specifically addressed with MEAs.

Dynamic Pricing
In conventional P&R decisions, list prices are fixed. In contrast, MEAs allow prices to be adjusted based on clinical performance, duration of treatment, dosage, and sales volume.

Evidence Generation
Coverage with evidence development (CED). Data generation to bridge the gap between traditional data requirements and limited evidence from MEAs.

Scientific Cooperation
The optimization and improvement of health policy is based on scientific cooperation between countries. Confidential MEAs prevent or hinder the comparison of prices, costs, and value.

Joint Procurement
The confidential nature of MEAs prevents joint procurement activities. Consequently, purchasing power cannot be strengthened by joint purchases, and small countries pay a higher price relative to their GDP, considering that parallel trade no longer works because of uniform list prices. Consequently, each country must define its willingness to pay. However, joint clinical assessments are still possible and joint cost-effectiveness estimates can be made for different discount levels.

Controlling Health Care Costs
Cost control affects governments, payers, service providers, but also patients. Government and payers know contract details of MEAs, while doctors and patients do not know the effective net price. This can affect doctors' prescriptions and patients' acceptance of treatment.

Window Price
The initial price offer from pharmaceutical companies may be higher because subsequent discounts are proactively included [6].

Transparency of P&R Decisions
P&R decision can be transparent, semi-transparent, or confidential. The lack or reduction of P&R transparency makes public price and benefit comparisons more difficult or impossible. Hidden negotiation with confidential net prices leads to higher prices than with a transparent process [4].

Administrative Burden
MEAs need to control and manage individual usage, costs, and outcomes. Associated with this is the need for additional human and financial resources. Digital processes will reduce the additional effort in the future.

When and how to use

New innovative treatment options address a high unmet medical need. Although existing data are limited, manufacturers expect a price that covers the full value of the new drug (list price). To allow earlier market access, prices are adjusted according to the current drivers of uncertainty, which may be epidemiology, clinical efficacy, dosage, duration of treatment and impact on the budget. In principle, MEA prices should be limited in time, adjusted upwards and downwards after the missing data become available. However, the upward scenario is hardly feasible in the current health systems. The prices of MEAs often do not change over time. This could mean that the MEA discount is, at least partially, included in the list price [6].

A New Normal? - Individualized P&R (Experience Switzerland)

Will the share of MEAs or pricing models of all drugs remain in the low single-digit percentage range? Probably not, because new drugs will primarily be complex, individualized biotech or CGTs products for the treatment of rare or ultra-rare diseases. In addition, these new products have much higher treatment costs, which means that their percentage of drug spending will be even higher than prescription volume. In fact, not only the treatment, but also P&R is individualized cf. [7].

" Not only the treatment, but also P&R is individualized"

Switzerland Experience [7]
Price models (MEAs) exist for 2-3% of the drugs in the Swiss positive list (SL). However, in the 2015-2022 period, 39% of new P&R applications for medicines used a pricing model. Drugs with an existing pricing model accounted for 15% of total drug costs in 2021. As of August 2022, there are 135 pricing models, of which approximately half are transparent and the other semi-transparent. The negotiation time for drugs with a pricing model is about twice as long as for drugs with a traditional P&R process. However, the treatment costs for drugs with a pricing model are about six times as high as for drugs without a pricing model.

" In the 2015-2022 period, 39% of new Swiss P&R applications for medicines used a pricing model. Pricing models accounted for 15% of total drug costs in 2021 [7]"

Consequences or how to deal with it?
A major criticism of MEAs is their confidential nature, which leads to a lack of transparency in pricing between countries. Consequently, the application of External Reference Pricing (ERP) is fading. Moreover, only the pharmaceutical companies know the net prices in the different countries, which strengthens their negotiation position and options.

How can payers and decision-makers adapt under such conditions? The first step is to identify the drivers of clinical and economic uncertainties; the second step is to create cost-effectiveness models for uncertainties with different drug prices or discount levels; the third step is to compare such models internationally; the final step is to define and defend your own value-based price range that considers country-specific circumstances.

Pharmaceutical companies and payer & decision makers will have their own models and value-based price range. Consequently, the negotiation phase is time-consuming and requires a lot of resources. All this diminishes the initial benefit of earlier patient access. For this reason, price negotiations should begin during the approval phase.

"Pricing models make P&R more global than national [4]". However, decisions remain based on a country-specific valuation and WTP."

Moving Forward - Solutions

- The main advantage of MEAs or pricing models is earlier access to new therapeutic interventions. However, a longer negotiation period compared to traditional P&R prevents MEAs from realizing their full potential [7]. The solution is to start negotiations with payers and decision makers at the advanced stage of the market approval process.

- Access of innovation should be fast, and pricing should be linked to data and performance in a dynamic way; this means lower price with preliminary data and higher price once full data and benefit assessment are available. Of course, this would need a policy change for dynamic pricing.

- Evidence generation should be rewarded. It is a major policy flaw if data generation is not rewarded with either a higher price or a significant rebate reduction. Without a reward, early access will continue to be based on limited data with a high degree of uncertainty and rising rebate levels. In addition, the innovation potential will not be fully leveraged cf. [8].

- For innovative medicines with high unmet medical needs, each country should confidently determine its price-performance rating and willingness to pay (WTP) to negotiate with manufacturers at the same level.

Limitation

This newsletter focuses on the pros and cons of pricing models. The purpose is to start a discussion about it. Completeness and correctness are not claimed; additions, corrections and comments are welcome.

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