NEWSLETTER

No. 7 / September 2017

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PAY FOR PERFORMANCE (P4P) OR JUST DISCOUNTS

Are pharmaceuticals getting a commodity as kitchen equipment with «moonshine» list prices and 40% discount? Do we really want to go this way and hope that our credibility is not affected?
P4P is a smart alternative where the manufacturer takes the risk of low performance in real life. Implementation is difficult, especially in terms of agreed endpoints. Even more, P4P reviews show little benefits (Mendelson, 2017; Milstein, 2016; Docteur, 2017, 3% savings). Discounts are a valid alternative but choosing the correct use and communicate it effectively is challenging.

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MULITI OPTION REIMBURSEMENT

Some years ago reimbursement decisions were for the majority of drugs just a yes or no decision within a well-established and transparent decision making framework. In our days both the pharmaceutical market and its regulation have significantly changed. Small Molecule Blockbusters have been widely replaced by Specialty-, Orphan-, Monoclonal- and specific Cancer drugs. Payers and Decision Makers are forced to challenge the value of every new technology to meet public and governmental expectations to control the continuously rising health care costs.

Payers and Decision Makers first concern was how to deal with medical and economic uncertainties at product launch. Payers agreed on potential long term benefits of a new intervention but feared the uncertainty about initial financial investment. Discounts were a simple commercial tool to

Table 1: Multi Option Reimbursement – selection of key elements

Market Access Agreements (MAA)	Type	Features	Description pros & cons
Price/Volume Agreement (PVA)	CA	• Supply/Demand • Win/Win • Dynamic Pricing • Limited new Evidence	Price/Volume Agreements are the most widely used MAA across Europe (40%; Kanavos 2017). Price is adjusted in relation to Volume. PVA is a Commercial Agreement (CA) tool to modify Budget Impact. PVA enables broader patient access right from the beginning with a limited requirement to deliver additional evidence.
Coverage with Evidence Development (CED)	OA	• Conditional Reimbursement • Data generation • Temporary	Coverage with Evidence Development (CED) is an Outcome Agreement (OA) tool to deal with the initial uncertainty about the clinical outcome and the financial consequences. It means conditional reimbursement with data collection in registries. If it works, full price will be maintained; if not price will be adjusted. Initial access of patient may be restricted. Delisting remains a potential risk (only conditional!). Benefit may be the high initial price.
Capitation (CAP)	CA	• Ceiling costs • Patient level • High cost patient	Capitation is a patient level Commercial Agreement to limit Payer's financial risk for high cost patients. This is especially useful for higher priced Orphan Drugs with unclear dosage and duration. CAP may lead to higher prices and broader access.
Pay for Performance (P4P)	OA	• Risk sharing • Pay backs • Data generation	Outcome is measured at the patient level. Full drug price is initially applied. Forms of financial pay back when clinical endpoints are not met or when clinical, adverse or hospitalization events occur. Demanding to set up and run. Low evidence of beneficial effect (Mendelson, 2017; Milstein, 2016; Docteur, 2017, 3% savings).
Confidential Discount	CA	• Differential pricing • Adjustment for cost-effectiveness • Launch enabler	The confidential domestic price is normally 20 to 29% lower than the External List Price (Morgan, 2017). This discounts can be flat discounts or tied to specific conditions. A discount of 20% should normally be sufficient to render a product cost-effective (Toumi, 2015). The drawback is lower launch price (probably not reversible).
Value adjusted Discount	CA	• Indication (multiple) • Lower Value	Official, non-conditional discount to get broader access for a lower value indication. Cost savings may be used up by admin costs. Risk of arbitrage.

Temporary or permanent Discounts?

That's really a key question! In general, discounts are hardly reversible and people get used to it and take it for granted. Of course, there are situations where discounts are a smart approach which can be easily explained. Offering a discount for a lower value indication is such a situation. Here the discount is just an adjustment for lower cost-effectiveness.

There are also possibilities to maintain the final justified price over time. P4P and Coverage with Evidence Development (CED) are the most widely used approaches. However, both are associated with additional costs, high administrative burden and limitation of access. Most important, the risk of failure to demonstrate clinical evidence exists; especially for CED there is a risk of delisting.

Temporary discounts are a fair tool to address the medical and economic uncertainty at time of product launch. After the evidence gap has been closed or the concerns about financial consequences have been overcome, the discount will no longer be granted. However, most stakeholders see this as a price increase which is difficult to communicate.

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first reduce Payers risk and second to speed up and enlarge patient access to promising new therapies. Discounts just improve the ICER and a 20 % discount should be sufficient to render most products to be cost-effective; however discounts can even be as high as 50 % or even more (Toumi, 2015; Aitken, 2016). Discounts do not reduce uncertainty nor do they close the evidence gap. Therefore discounts are hardly reversible and a permanent lower product price is the consequence. P4P is a much smarter approach and starts at full drug price with some kind of payback in case of low drug performance. However, P4P is not always suitable; a higher level of evidence and benefit is required. P4P is demanding to set up & run and shows low evidence of beneficial effects (Mendelson, 2017; Milstein, 2016; Docteur, 2017, 3% savings). Coverage with Evidence Development (CED) is probably the best way to close the evidence gap and generate the required data to justify and maintain the initial price level.

Managed Entry Agreements, Patient Access Schemes, Risk-Sharing Agreements and P4P are widely used terms to describe above arrangements (see Table 1). To name it simple «Market Access Agreement» (MAA) and acknowledge that MAA's are mostly a mix between commercial agreements and P4P, as proposed by Toumi (2017), is in our view the most appropriate definition.

> Choosing the right meal form the reimbursement menu will become a striking competitive advantage.

Most countries have implemented different MAA's in different ways leading to a heterogeneity in pricing and reimbursement decisions (Pauwels, 2017). Comparison of deals and real market prices are not easy but give both Decision Makers and Pharmaceutical Companies the opportunity to choose from a broad menu of reimbursement strategies (Edlin, 2014). Choosing the right meal form the reimbursement menu will become a striking competitive advantage.

TOTAL VALUE PRICING

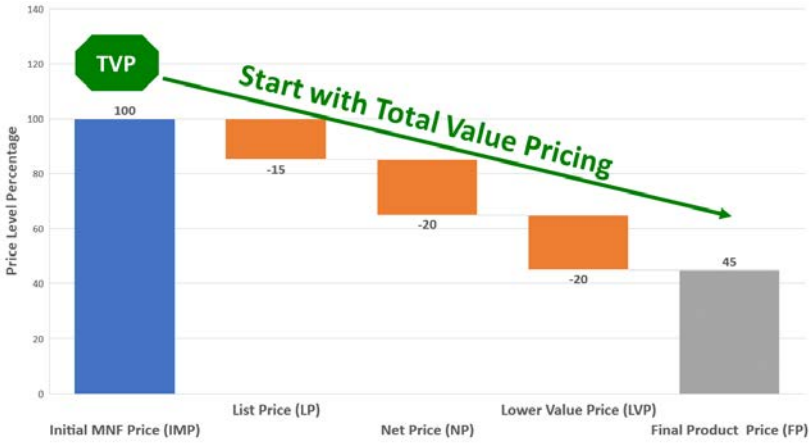

Figure 1: The Discount Cascade - fictitious example to illustrate

Value is defined as cost per outcome and depends on the Willingness To Pay (WTP). Every stakeholder has his/her individual perspective and consequently a different WTP. To maximize product price, it is advisable to maximize the value perception for each stakeholder including all potential medical, economic and private benefits before sum them all up in a general societal perspective. By doing this you will get to know the Total

Probably no Country can afford to compare List Prices

Confidential price discounts are usually a part of a Market Access Agreement (MAA) and quite common across Europe (Morgen, 2017). Confidential discounts allows the manufacturer for price discrimination across markets. Payers and Decision Makers ability to negotiate may get more important than their ability to pay. Confidential discounts will increase the demand for explicit discounts in other countries. This will accelerate the process of fading away the concept of External Price Referencing (EPR) as a benchmark tool for price negotiation in countries not using cost-effectiveness as a decisive criterion. We will probably first face an adjustment of the ERP country basket before ERP will be replaced by another, yet unknown system.

Also countries like Switzerland with a transparent P&R system of list prices cannot afford to pay average European list prices in a long run. The starting point for negotiations will be discounted list prices. This is the very reason that MAA's will become a new standard process for new health technologies. Again, P&R will not become easier but much more complex and additional capabilities are required to deal with it successfully.

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Value Pricing (TVP) of your drug with its corresponding maximal price level. As we know from the Hepatitis C breakthrough therapy, there is still a different attitude and controversy towards separating value and affordability. In our view for final decision making both value and budget impact have to be considered, however, TVP has to be assessed and honored in a first and separate way. The Initial Manufacturer Price offer may already include some concessions for the key countries decision frameworks (e.g. only considering direct medical benefits and costs). The following negotiation will end up in a lower List Price for which the true product value is already in the process of fading away. Further discounts are requested

The most frequent discounts to List Prices are between 20 % and 29 % but up to ≥ 60 % (Aitken, 2016; Morgan, 2017).

to compensate for a real-life evidence gap and to reduce utilization restrictions. Multi-Indication Pricing is emerging as many new drugs will have multiple indications with different values over time. At the end, some drugs will have only 50 % of their initial price and the accepted starting price level is of utmost importance (Figure 1).

DISCOUNTS TO DEAL WITH UNCERTANTY AND LOWER VALUE INDICATIONS

One major concern of Payers and Decision Makers is that the rising tendency of discounts will just lead to higher list prices (Gellad, 2017). For pharmaceutical companies there is a great temptation to do so (Figure 2). However, rising list prices will probably cause a political and public outcry. In addition, the rising discount levels may undermine the credibility of pharmaceutical pricing and Payers and Decision Makers will anticipate significant discounts just from the beginning (Pauwels, 2017). They reject an initial price proposal as they are heading for a more attractive Market Access Agreement with lower price (Kanavos, 2017). The initial idea for discounts was to reduce uncertainty and financial risks for Payers until full evidence is available. These discounts were thought to be temporary but may be difficult to reverse.

Figure 2: The List Price-Discount reinforcing loop

These days' higher additional discounts are also offered to facilitate patients' access to lower value indications. A pilot study shows that discounts are used up to a large extend by Payer's admin cost (Roche Symposia, HTAi Rome 2017). Consequently Payers will ask for much more discounts in the future. This process needs to be made more straightforward. Digitalization and coding could offer potential solutions. The idea to adjust for cost-effectiveness only with a lower net price for lower value indications will hardly be accepted by authorities. Adjustments have to be made for volume, budget impact & transactional costs (Towse, 2017).

Digitalization and coding may help to keep discounts within a certain limit by lowering admin costs.

A Coding-System for Pharmaceuticals?

List prices are a one size fits all principle. Multiple indications and Precision Medicine are asking for specific and individualized P&R solutions. Market Access Agreements are suitable to modify the current P&R system. However, their administrative burden is quite cumbersome.

Why not have a look at the P&R-system of Medical Devices. A DRG is the result of disease and procedures with fine tuning based on patient's characteristics like age, severity and complexity.
A «Pharma-DRG» would be the sum of points representing product's value whereas the payment for a point would be negotiated. By doing so drug prices could be individualized. Above concept should provide only food for thought. However, a new system to account for individualization of drug therapies should probably be developed.

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CONSEQUENCES IN PRACTICE

- P&R will often translate into a Market Access Agreement (MAA)
- MAA's are complex and will increase Manufactures' uncertainty
- Discounts are hardly reversible – consider CED
- Countries can't afford list prices – rising demand for discounts
- External Price Referencing (EPR) is loosing its benchmark value
- Price-Volume-Agreements may be the most suitable MAA

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- **Modular Services** (tailor made) :
  Value Dossier, Pricing Strategy, Stakeholder Management, Value-Testing, Budget-Impact (OKP), Payer Marketing, Patient Engagement etc.

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