Pricing & Reimbursement

Does Pricing & Reimbursement still belong together?

- or -

Do we need different approaches?

It is a rather provocative question of whether pricing & reimbursement still go along together or should be approached and managed in a different way. First this position paper will shortly review P&R tendencies, second it will discuss the changing key drivers for P&R and finally it will outline potential new directions in P&R. Overall we favor the idea that P&R go along together during the launch phase but should be managed differently to some extend during the market uptake and maintenance phase.

From international and therapeutic benchmarking to value for money

We see a reasonable price convergence in Europe today both for new products at launch and for marketed drugs

The accepted value for money and the agreed level of innovation are now the drivers for P&R

Over the last decade soaring health care cost and double digit growth rates of pharmaceuticals have led to a continuous flow of pharmaceutical policies across nations. The key objective was to control costs by a national mix of supply and demand side measurements including e.g. rebates & discounts, reference pricing, budget control, co-pay levels and promotion & incentives to prescribe and use generics etc. However, the focus was clearly on external price referencing (international benchmarking). Numerous price comparison studies were conducted to demonstrate international price differences which have been developed over the years. In addition international initiatives were launched to increase P&R transparency[i,ii,iii]. As a consequence, we see a reasonable price convergence in Europe today both for new products at launch and for marketed drugs. This international pricing alignment resulted in national efficiency gains and created some headroom to finance innovations. However, this savings are not large enough to cope with the ongoing cost constraints. Therefore the focus has shifted to internal price

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referencing (= therapeutic benchmarking). The price of a new drug and its disease treatment costs are compared with existing therapies. Of course therapeutic benchmarking has already been done in the past but today we benchmark also with well established generic alternatives and the bar for an innovation premium has been raised substantially. The accepted value for money and the agreed level of innovation are now the drivers for P&R.

P&R is a scientific not an economic challenge

The potential of external and internal price referencing (international and therapeutic benchmarking) has been mostly realized. Additional medical benefit and economic impact must now be clearly demonstrated with e.g. HTA, EBM and HEOR reports. Also Germany, one of the last bastions of free pricing, changed its law. Applicants must now demonstrate an additional medical benefit for a new drug; otherwise the drug will enter the reference price group. If the G-BA (Federal Joint Committee) agrees on additional medical benefit, a rebate on the initial manufacturer price will be negotiated between the pharmaceutical company and the association of health insurer. This approach shows a system between a "scientific regulation" and market driven price negotiation. In Germany, France and most other countries the key driver for P&R is the demonstration of additional medical benefit. Additional medical benefit is the prerequisite for any economic consideration as affordability and cost effectiveness. The key objective is now how to demonstrate additional medical benefits which is especially a challenge for incremental

1. **Additional medical value**
   - CER, RCT
2. **Innovation classification**
   - Innovation or reference group
3. **Evidence**
   - HTA, EBM, real life data
4. **Benchmarking**
   - External price referencing = international benchmarking
   - Internal price referencing = therapeutic benchmarking
5. **Quality of life**
   - Patient reported outcome
6. **Health Economy**
   - Cost effectiveness, Budget impact, Economic modeling

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innovation. In general we see stakeholder's different value perception as key barrier for success. Addressing and satisfy key concerns proactively will be the ground for alignment of value perception.

Close the value gap by aligning stakeholder's value perception

Value for money is the key driver for P&R. Value is the additional medical benefit balanced by product price and treatment costs. What really matters is the value gap between the pharmaceutical industry and both payer and decision makers. It is of utmost importance to close this gap in order to achieve optimal P&R. First a global value dossier must be adapted to the national framework of health care. This means that we should not only adjust for national data but also take into consideration different regulations, HTA's, treatment patterns, cost structure, concerns and attitudes. Second we have to identify and visualize key stakeholders and their cause-effect relationship. Third we should identify and manage their concerns with stakeholder specific data such as e.g. budget impact study, health economic studies, drug usage, real life data etc. Forth we should help stakeholders to manage their unresolved concerns e.g. with utilization control, outcome management or aid to limit financial risks. These activities are best done in a cooperative partnership with stakeholders.

Additional medical benefit must now be clearly demonstrated with e.g. HTA, EBM and CER reports

Cost effectiveness and other HEOR reports do only matter if an additional medical benefit is accepted

Different value perception of stakeholders is the key barrier for success. Addressing and satisfy key concerns proactively will be the base to align value perception

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What is then left to pricing?

We do have a pricing issue in two different phases; first when it comes to P&R decisions and second during market uptake and price maintenance. The price is the counterpart of additional medical value. A higher price lowers the value of an additional medical benefit both for payer and decision makers. A higher price can be justified by a high level of innovation and evidence, a more severe disease, the lack of alternatives, a low number of patients and the potential of economic savings. However, it remains a challenge to explain different prices for different indications or diseases although the reasoning behind is clear with different therapeutic benchmarks, different levels of value generated and different market sizes.

The price is the counterpart of additional medical value

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Price levels can be kept relatively stable if the value proposition can be supported continuously with new evidence and real life data

Once the initial price has been set the objective is to gain fast market uptake. Again, demonstrating evidence is the prerequisite but pricing plays also a critical role to get listings and contracts with provider or payer organizations. The ability to identify stakeholders and decision makers, the method of getting access to them and the experience of smart contracting will gain momentum.

The long term objective for a company is to maintain the price level during the on patent period and to manage generic competition in the off patent life cycle. Price levels can be kept relatively stable if the value proposition can be supported continuously with new evidence and real life data. Price adjustments are enforced by regulators or driven by market forces (rebates & discounts); for both, evidence and real life outcome data will strengthen the company's position.

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Last but not least pricing strongly depends on the national pharmaceutical policy. Therefore it is of utmost importance that pharmaceutical associations are in continuous interaction with regulators to create a sustainable health care environment for all stakeholders.

Key positions

pharmaLevers puts the following statements up for discussion:

- Demonstration of additional medical benefit is the key driver for P&R. This is a medical and not an economic issue
- The ability to change and align stakeholders value perception will divide successful companies from others
- The pricing focus will be negotiation and contracting with integrated provider networks for market uptake and price maintenance
- Pricing and reimbursement still belong together but need different approaches and capabilities

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References

[i] Espin J. and Rovira J. (2007). Analysis of Differences and Commonalities in Pricing and Reimbursement Systems in Europe. A study funded by DG Enterprise and Industry of the European Commission. Andalusian School of Public Health.

[ii] Vogler S. et al. (GÖB/ÖBIG) (2008). PPRI Report (Pharmaceutical Pricing and Reimbursement Information). Commissioned by European Commission, Directorate-General Health and Consumer Protection and Austrian Federal Ministry of Health, Family and Youth.

[iii] Docteur E. and Paris V. (2008). OECD Health Policy Studies. Pharmaceutical Pricing Policies in a Global Market. OECD.

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