

Marketing Economics

Pricing and reimbursement: Towards a holistic approach

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Abstract As health care systems are continuously fragmenting into diversified care models with underlying specific cost models, pricing and reimbursement is becoming an increasingly complex issue for drug companies. The main challenge is to incorporate a payor's perspective into price calculation while pinpointing the adequate product value. This paper describes the situation in Germany and proposes a multi-dimensional model enabling companies to create a decision algorithm leading to more precise individual pricing and thus a stronger position in reimbursement negotiations.

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INTRODUCTION

Pricing and reimbursement of new and available drugs and medical devices is a continuously growing challenge for manufacturers. This is especially true for the markets in the European Union. The companies are facing a growing regulatory thicket imposed by national and regional authorities, either driven by statutory and private insurers or by governmental institutions. As reimbursement in the early 1990s was tagged as the *4th hurdle* after marketing authorisation by medical agencies, in some countries governments and payors are continuously implementing

5th and even 6th hurdles in order to impose restrictions on prescribers and/or to drive them into 'rebate loops'. Industry-wise the pricing-process is covering all departments from business development, outcomes research, sales and medical with a strong need for harmonisation and standardisation of corporate and affiliate operations.

THE GERMAN LESSON: STATIC PRICING UNDER PRESSURE

Germany is a compelling example for rising pressure on drug pricing. While

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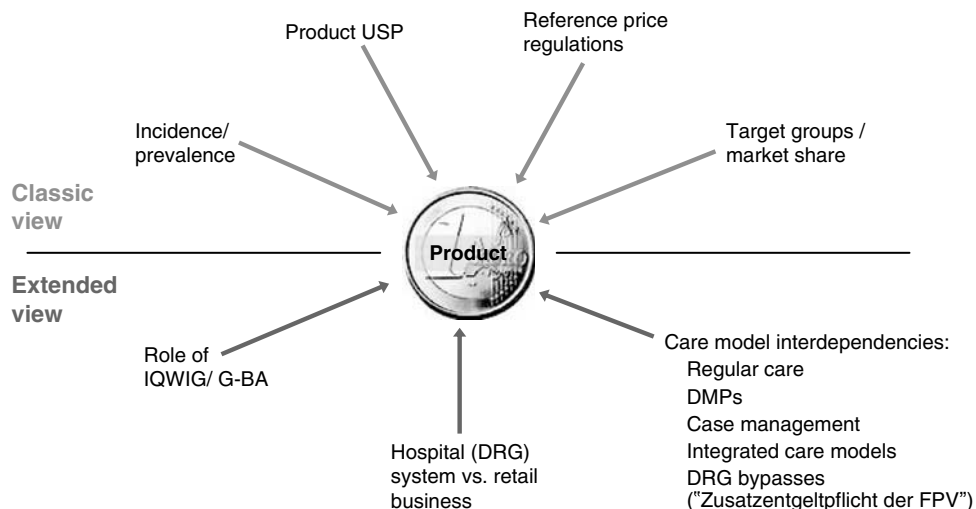


Figure 1: Example Germany — though pricing/reimbursement looks straightforward, a multi-variate view on pricing is fundamental

off-patent drugs are regulated by a complex reference-pricing system, patent-protected compounds once were considered to be ‘easy-to-price’. The German government is, however, increasingly influenced by the insurance companies. Among the changes initiated during recent years, the following measures have direct influence on the industry (Figure 1):

- An institute for evaluation of quality and cost-effectiveness of healthcare (IQWiG), formed in 2004, is monitoring and evaluating if prices and reimbursement of drugs are justified in defined therapeutic areas based on clinical evidence and outcomes research. Although the IQWiG does not yet have power to withdraw reimbursement status, its recommendations have gained an informally binding character to German insurers. The pharma companies’ associations and lobbying organisations are struggling to agree on the standardised criteria of the institute on evaluation of drugs.
- Since 2007, the German statutory health insurances are authorised to negotiate rebate programmes with drug manufacturers. This legal change is significantly affecting the traditional model of pricing authority.

- Elements of integrated healthcare and disease management were introduced early in the decade. These are focusing either on specific indications (diabetes, hypertension), re-allocation of resources from specialists to GPs and/or development of regional networks with capitation remuneration. All these models are influencing the traditional pricing models, since payors have partial power to either (re)negotiate prices or to simply exclude drugs considered to be non-cost-effective in the specific models.
- As the German hospital system was switched to DRG-based reimbursement, drug prices, predominantly for expensive specialties in oncology or immunology, have become sensitive. While certain drugs may be covered by additional funds, other high-priced compounds may be excluded from individual formularies. Meanwhile, hospital pricing is coming under pressure with individual hospital pharmacies pushing for rebates.

THE IMPACT ON PRICING AND REIMBURSEMENT STRATEGY

In Germany, the changes mentioned above directly influence the industry’s strategy on pricing and reimbursement negotiations.

As ‘classical pricing’ was mainly dominated by consideration of market size, targets and competition, the fragmentation of care models is making decisions on price corridors in individual territories extremely complex. On the other hand, reimbursement negotiations are becoming more and more dynamic. Initial approval does not guarantee continuous reimbursement anymore. Pharmaceutical companies are recognising that the European markets are rapidly turning to a *payor-centric* model requiring a sophisticated approach to price building with subsequent reimbursement procedures. Governmental and insurance authorities have acquired strong medical and economic skills enabling the payors to increase pressure on drug manufacturers. Therefore the industry is forced to build new partnerships and networks and gain perspective on the payor mindset.

PRICING STRATEGY: BUILDING A TOOL FOR COHERENT REIMBURSEMENT

Leaving the classical push-oriented pricing strategy requires a multidimensional view on the socio-economic setting in the individual countries. The key drivers to be addressed are listed in Table 1.

These factors have to be included into a semi-quantitative input model incorporating nonparametric data that are itemised and weighted. Thus, companies are enabled to create a decision algorithm in order to achieve precise individual pricing and to strengthen their position in reimbursement negotiations. The results of this process are displayed in a decision matrix. Furthermore, the model permits dynamic usage, that is recalculation of prices, if regulations or market conditions will change. Figure 2 depicts the process

Table 1: Key drivers for determining a coherent reimbursement strategy

Category	Key drivers	Variables for input model*
<i>Regulatory requirements</i>		
	<ul style="list-style-type: none"> • Regulatory framework <ul style="list-style-type: none"> ○ Payor infrastructure ○ Governmental ○ Autonomous price committees 	N
<i>Commercial setting</i>		
	<ul style="list-style-type: none"> • Market size • Individual country market potential/ market share estimate • Lifecycle • Competition/comp. pricing • Expected product USP • Supply chain (threat of parallel trade, dilution of retail market by hospital supply) 	P P P N N
<i>Clinical and pharmacoeconomic value</i>		
	<ul style="list-style-type: none"> • Innovation vs me-too • Availability of outcomes model • Clinical evidence • Guideline compliance 	N N N/P N
<i>Health care setting</i>		
	<ul style="list-style-type: none"> • National and regional health care framework • Purchasing networks • Hospital vs retail infrastructure • Allocation of additional budgets 	N N N N

*P, parametric; N, non-parametric.

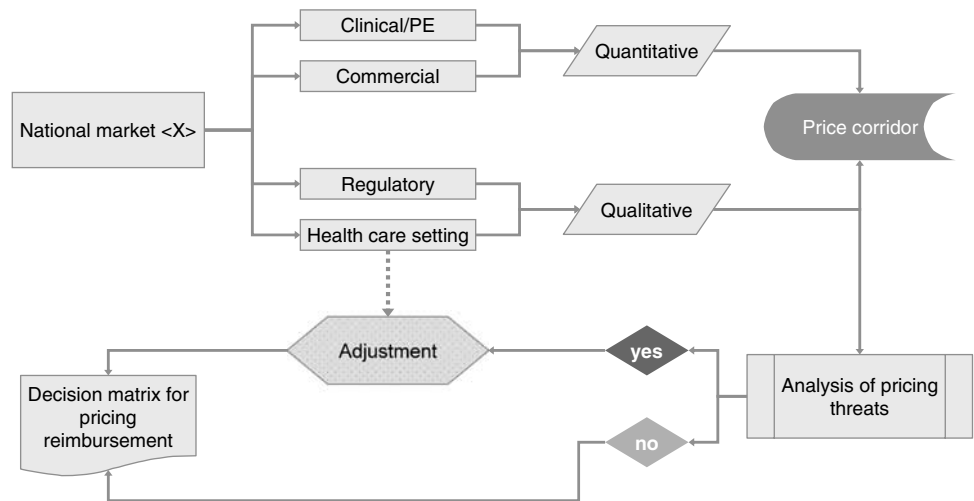


Figure 2: The price building process

of price building based on this methodological approach.

By characterisation and integration of multi-perspective issues, the industry will be enabled to accelerate internal pricing

processes as well as subsequent reimbursement negotiations. Thus, the proposed methodology represents a valuable model for integration of payor/governmental perspective as well as revenue-driven objectives.