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Levers for change

The influence of new stakeholders over medicine prices in Germany is escalating

Just a few weeks ago, reforms to the German healthcare system came into effect bringing profound changes to the market for pharmaceutical companies. Cost-benefit analyses and compulsory second opinions have been introduced to the prescribing process, and payers and care providers now have more power to negotiate. This will affect pharmaceutical products throughout their entire life cycle.

To some extent, the pharmaceutical industry had already begun to adapt its working practices and processes in line with these changes – a necessary move if it is to remain competitive. However, a continued and structured approach to this change process is crucial if key factors such as market access and health economics are to be integrated into business strategies. With change comes opportunity, and pharma companies need to act now to gain a headstart advantage in the emerging environment.

Illustration by Rob Wilcockson

EXPENDITURE CURBS

Levers are located throughout the decision-making process to determine whether a drug reaches the patient – beginning with drug approval and ending with patient compliance. Previous reforms focused on the levers towards the end of this process (eg, applying pressure on physicians to prescribe generic drugs). Unsurprisingly, the new reforms seek to pull the levers with the greatest impact on drug expenditure.

However, the current reforms introduce elements throughout the entire process, targeting both fast-growing markets and larger, more established therapy areas. Those elements of the reform that will have the greatest impact on the drug industry are shown in figure 1 (opposite); most of these can be categorised by their influence either on price or on prescribing behaviour.

NEW INFLUENCES

The lack of price regulations has made Germany a favourable marketplace for pharma companies but these new reforms mean that drug prices will be increasingly influenced by other stakeholders.

Flexible price negotiations and more negotiation power for payers will put pressure on the price of pharmaceuticals, and health insurance providers, such as Allgemeine Ortskrankenkasse (AOK), will use their increased powers to improve their profits.

In the past, German authorities only assessed the efficacy of drugs but cost-benefit analyses will look now at whether they provide real value for money. These changes will have the greatest impact on expensive products, such as cancer drugs, which legislation has had little control over historically. The reforms will influence prescribing behaviour with obvious and significant effects for pharma companies. Tighter restrictions on the use of prescription data will make it more difficult for drug firms to manage their salesforces. As data in the finest detail will no longer be available, salesforce impact can now only be measured from aggregated data.

Physicians who are willing to prescribe certain high cost drugs now face an added hurdle of soliciting a second opinion. Payers and care providers will therefore exercise a growing influence on drug listings and cost-benefit analyses will be used to justify the choices made. In addition, to keep their co-payments lower, insured persons will have more incentive to influence physicians to prescribe less expensive medicines.

PRODUCT IMPACTS

Whether the market is established or still growing, cost containment is high on the agenda for the payer. A recent analysis of the top 27 Anatomic Therapeutic Chemical (ATC) classes in the German market highlighted those on which cost containment had impacted most heavily.

It also identified product classes hit by previous healthcare reforms. Primary care products, such as antihypertensives and drugs used to treat diabetes, have generally exhibited lower growth, but because of the huge number of patients in these groups they are still extremely important to payers. Previous reforms have resulted in a reduced market for former leading product classes, such as lipid-modifying drugs and calcium channel blockers.

Neither payers nor the authorities select products arbitrarily, making it crucial to analyse the parameters determining the extent that current reforms will affect a product. Above all, drug companies which operate in the markets affected by the reforms must adapt to accommodate the changes that lie ahead.

TARGETED BY PAYERS

Put simply, payers have in the past focused on the cost drivers in large markets. In July 2006, the Federal Committee (Gemeinsamer Bundesausschuss) decided that the cost of short-acting insulin analogs will only be reimbursed if it is equal to that for human insulin. This decision was based on an analysis conducted by IQWiG (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen), the German equivalent of the UK's National Institute for Health and Clinical Excellence (NICE).

Some health insurers then seized the opportunity to negotiate rebates with drug companies. This gave them a competitive advantage by letting them offer innovative drugs to their clients.

Another IQWiG analysis focused on the use of the blood thinner Clopidogrel to prevent myocardial infarctions. Following publication of the report, the Federal Committee agreed in principle on the use of Clopidogrel as a monotherapy. The Federal Ministry of Health (BMG) reviewed and repealed this decision only after serious complaints.

VALUE ANALYSIS

In the UK, NICE has been performing cost-benefit analyses since its inception in 1999. Such analyses have proved to be a valuable tool in curbing the outlay on expensive medicines, such as cancer drugs and medication for rheumatoid arthritis. This demonstrates the possible impact of analysis on individual products.

In August 2006, NICE published a negative decision regarding the use of Cetuximab, a monoclonal antibody against colon cancer, arguing that the National Health Service should not reimburse this treatment.

The introduction of cost-benefit analyses will cause the IQWiG to focus more broadly on drug indications, thereby targeting indications that have previously been considered as 'leave alone' areas.

Evidently, the current reforms are already having a dramatic impact. In February 2007, the AOK negotiated new rebates for a large proportion of its drug portfolio. The contracts comprise rebates for 43 agents and agent combinations, the prices of which will be up to 37 per cent below the current retail price.

Interestingly, most of the contractual partners are small and relatively unknown market players. Taken together, these pharmaceutical partners add up to a market share of no more than 1.3 per cent. Such companies clearly intend to use this kind of contract to gain a foothold on the German drug market.

Other health insurers operate different negotiating strategies, however; for example, VdAK (the umbrella organisation of the seven salaried employees' health insurance funds) demonstrated a highly focused approach by issuing a tender for nine specific substances.

Another insurer, TK, intends to adopt a more collaborative approach and negotiate prices across a drug company's entire portfolio.

WIDESPREAD EFFECTS

Having identified the parameters that determine the effects of the healthcare reform, Roland Berger Strategy Consultants analysed the top 100 drugs in the German retail market to see how the changes ahead could affect them.

The combined revenue of these drugs currently totals €8.7bn. Close analysis showed that a large proportion of these drugs will be affected to a significant degree. Aspects such as payers' increased negotiating power alone will affect more than 60 per cent of total revenues.

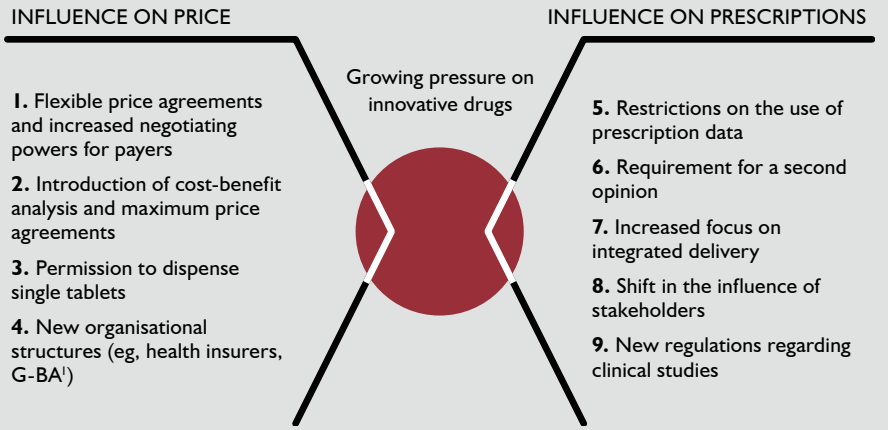
Equally critical is the increased freedom of care providers to influence drug listings. Medical-benefit and cost-benefit analyses predominantly affect first in class products – those early in their life cycle. By contrast, price differentiation (through rebates) and changes in listing practices will mainly affect products that have generic competition – those late in their life cycle.

The impact on individual drugs depends on their financial characteristics, but also on their life cycle phase. Pharma firms must therefore engage individual stakeholders in dialog regarding their product portfolios. It is vital that they adopt a structured approach when addressing key stakeholders.

New customer groups are emerging and gaining influence, such as second opinion physicians who review prescriptions for expensive drugs. To accommodate this shift in the importance of stakeholders, cross-functional processes for product management, market access, medical affairs and key account management will be necessary. If they have not already done so, drug firms will need to build up internal expertise in market access and health economics, and then integrate these skills into their business strategies.

Overall, the potential effects of the current healthcare reforms are substantial. The regulatory changes will affect drugs at all stages of the product life cycle. Key players in the pharmaceutical industry have already established structures and processes in response. Such astute and proactive moves will doubtless reinforce their competitive position once the full effects of the reforms unfold.

FIGURE 1: HEALTHCARE REFORM EFFECTS



1) Federal Joint Committee (Gemeinsamer Bundesausschuss)

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