While Germany has long been one of Europe’s most attractive pharmaceutical markets thanks to free pricing, this is set to change soon under new regulation with particular focus on price negotiations for patent-protected drugs.

**GERMANY AT A GLANCE**

- **Area:** 357,021 km²
- **Population:** 81,757,000 million
- **Population growth:** 0.14 per cent
- **GDP (nominal):** $3,352bn (2009 estimate)
- **GDP growth:** -4.9 per cent (2009 estimate), +2.2 per cent (Q2 2010 estimate)
- **GNP per capita (nominal):** $40,874 (2009 estimate)
- **Healthcare expenditure as per cent of GDP:** 10.5 per cent (2008), >11 per cent (2009 estimate)
INTRODUCTION

Germany has been nicknamed the ‘Pharmacy of the World’ because a number of important substances were discovered and synthesised here for the first time on an industrial scale. Germany is the home of Merck KGaA, the world’s oldest pharmaceutical manufacturer, founded in 1668. It also boasts almost 80 Nobel Prize winners in science.

Bismarck’s introduction of a social system in 1883 was regarded as a revolutionary achievement and marks the foundation of the present healthcare system. It guarantees people covered by social health insurance access to drugs, regardless of their financial circumstances.

Germany is the largest pharmaceutical market and by far the largest market for generics in Europe. The Business Environment Rating (BER) published by Business Monitor International still sees Germany as the most attractive location for pharmaceutical research and production in Europe in 2010. Germany ranks fifth in terms of locations most favoured by the pharmaceutical industry after the US, Australia, Canada and Japan, but it has lost ground in recent years to the US and Japan. An increasingly regulated home market and changes regarding pricing structure and reimbursement are factors limiting growth prospects.

Yet the industry still occupies a prominent position in the German economy, both in terms of value creation, at over €100,000 per employee, and in terms of innovative energy it still tops the rankings ahead of IT and the car industry. As with other industries, high wage levels are concentrating the focus on research-intensive, high-quality products. Costs of research and development (R&D), amounting to around 13 per cent of turnover and accounting for around 10 per cent of the total research expenditure in Germany, reinforce this trend.

These high levels of expenditure are triggering a lot of other service providers to collaborate in R&D. Moreover, clinical development in Germany is also profiting from high medical quality, a close network of study centres and a cost advantage of around 50 per cent over the US. These factors have assured Germany’s leading position in commercial clinical research in Europe. And because of its geographical proximity, clinical research projects in price-attractive regions such as Central and Eastern Europe are often coordinated from Germany.

The pharmaceutical industry employs over 110,000 people, 17.3 per cent of whom are in R&D. These highly qualified staff are trained in 343 universities which turn out 70,000 new graduates a year in biology, chemistry and engineering sciences.

Although Germany covers every link in the pharmaceutical value chain, and a major proportion of the international R&D centres are established here, none of the global top 10 pharmaceutical companies is based in Germany.

Among the manufacturers founded in Germany, many are still family-run or are in the hands of founder families. Boehringer Ingelheim and Merck, two of the largest German pharmaceutical companies, are family businesses. Even global niche suppliers such as Grünenthal, in the field of pain treatment, or Mertz, in the field of neurology, are family-run to this day.

Family ownership may offer some protection from takeovers. However, not even this owner structure can escape the trend toward consolidation, as shown by the Schwarz Pharma takeover by Brussels-based biopharma company UCB in 2006.

A number of other traditional German suppliers have disappeared from the market as a result of mergers. In 1992 Berlin-Chemie was taken over by the Italian Menarini; in 1997 Boehringer Mannheim was bought by Roche; Knoll went to Abbott in 2001, and Hoechst AG was merged first with Aventis and finally with Sanofi-synthelabo to form sanofi-aventis. With the merger of Bayer and Schering, two of the oldest German pharmaceutical manufacturers lost their independence, but together they are successfully holding their own top slot among the pharmaceutical manufacturers established in Germany.

MARKET OVERVIEW

In 2009, pharmaceuticals worth €42.2bn were purchased in Germany. Of these, about 11 per cent were for self-medication and about 12 per cent related to private medical insurance prescriptions.

Some 87 per cent of the expenditure is borne by the social health insurance system and constitutes the Gesetzliche Krankenversicherung (GKV), known as the ‘GKV market’. For the most part, the expenditure is financed by the social health insurance system itself (86.4 per cent), but is also funded by percentage excesses paid by the insured (5 per cent) and by discounts off the official price (8.6 per cent) granted by pharmaceutical manufacturers.

The proportion of manufacturers contributing to the gross turnover of finished pharmaceuticals in the GKV market is only 56.1 per cent. Wholesalers earn around 3.5 per cent of the turnover and pharmacists 15.2 per cent. Legally prescribed deductions and agreed discounts knock about 9 per cent off the official price. The full value-added tax rate of 19 per cent has been applied in Germany to pharmaceuticals since 2007, which means that the proportion of tax on gross turnover is 16 per cent.

In the GKV market, the growth in turnover has been around €1.3bn, mainly due to higher consumption (+€1.1bn) and the switch to innovative preparations (+€0.4bn). Price rises contributed only €0.2bn to the growth in turnover. This growth has been partially compensated by the prescription of larger packs and by price reductions for substances that lost their patent protection in 2009.

In 2009, the strongest classes of substances (according to the Anatomical Therapeutic Chemical [ATC] classification system) were those for the central nervous system, at €4.3bn, the digestive tract/metabolism and the cardiovascular system, at €3.3bn each, and antineoplastic and immune modulators, at €3.2bn.

The two strongest products in Germany, in terms of turnovers at the manufacturer’s selling price, are TNF-alpha inhibitors for treating rheumatoid arthritis – Humira, at €310m, and Enbrel, at €265m. These are followed by tyrosine kinase inhibitor Gleevec, at €208m, for the treatment of chronic myeloid leukaemia. Positions four and five are occupied by the respiratory-tract therapeutics Symbicort and Spiirva, each at around €202m. Finally, Rebif and Copaxone, used for treating multiple sclerosis, occupy positions six and seven.

Drugs for rheumatoid arthritis (including other systemic diseases) have seen the highest growth rate, with an increase of €203m, together with neuroleptics and antipsychotics, with an increase of €154m and cardiovascular disease, with a jump of €140m. Pharmaceutical expenditure for multiple sclerosis, asthma and COPD, as well as cancer diseases, is also increasing sharply.

Reductions in turnover are being seen mainly in vaccines. For example, the turnover in vaccines for early summer meningoencephalitis fell by nearly €90m, and expenditure for vaccination against human papilloma virus (HPV) decreased by €130m after the primary target group had been comprehensively vaccinated.
MARKET OVERVIEW CONTINUED

Because of the patent expiration for Pantoprazol, turnovers in the area of indication acid-related diseases also fell by €97m.

Biopharmaceuticals now have a turnover share of approximately 16 per cent of the German market and, in the clinic, the turnover share of biopharmaceuticals is as much as 26 per cent due to the high proportion of antineoplastics in the inpatient sector. The areas of metabolism (mainly insulins) and immunology contribute around a quarter of the total turnover of €4.6bn in biopharmaceuticals in pharmacies and hospitals (at the maker’s selling prices). These are followed by central nervous system and oncology drugs. While, in 2007, the market for biopharmaceuticals grew a further 28 per cent, the growth in turnover in 2009 was only around 5 per cent – due not least to the increasing use of biosimilars.

Generics now account for 63 per cent of the sales volume in the GKV market, patent-free original suppliers account for 15 per cent and patent-protected pharmaceuticals or pharmaceuticals without generic competition 22 per cent. Based on a European comparison, Germany therefore occupies top position in terms of the generics share and lies behind only the US and Canada. In the case of expenditure, the situation is the reverse, with patent-protected pharmaceuticals accounting for 58 per cent of expenditure in the GKV market, generics 28 per cent and patent-free originals still at 15 per cent.

The sale of parallel imports has been promoted by the German government since 1989. Pharmacists are obliged to sell imported pharmaceuticals in preference at favourable prices. While in 1998 the market share of parallel imports was still less than 2 per cent, this has now risen to almost 11 per cent. International manufacturers of innovative products are being hit particularly hard by re-imports. The share of parallel imports of the total corporate turnover in Germany for Lilly is over 35 per cent, Roche 27 per cent and GlaxoSmithKline 24 per cent. Although the planned increase in the compulsory discounts has led to a situation where the purchase price abroad exceeds the selling price that can be achieved at home – meaning that imports are no longer worthwhile – it must not be assumed that the statutorily initiated price reductions relative to innovative pharmaceuticals have so far been affected by parallel and re-imports.

When price levels in the pharmaceutical market were last compared, in June 2010, Germany had the third highest prices, exceeded by Belgium and Ireland. Sweden, Norway and the UK had the lowest.

GOVERNMENT HEALTHCARE POLICY AND EXPENDITURE

The total healthcare expenditure in Germany in 2008 amounted to €263bn – equivalent to 10.5 per cent of GDP. It is assumed that this share increased in 2009 to around 11 per cent (data yet to be provided). Germany therefore lies far above the OECD average of 8.9 per cent. If GKV expenditure is taken alone, the proportion of GDP is 6.45 per cent.

Pharmaceutical expenditure, at 16.8 per cent, represents the second largest item of the GKV budget after inpatient treatment, so general policy is focusing more than ever on reducing these costs. A total of 20 healthcare reforms have been passed by the respective regional governments to cut costs. As part of these reforms, a variety of instruments have been established to control pharmaceutical prices. The most important are:

- Compulsory discounts and price moratoria
- Additional payments by patients
- Obligation to sell imported drugs
- Maximum and fixed refunds
- Benefit evaluations
- Economic analyses
- Manufacturer discount contracts.

With the last-mentioned of these, the system based on collective agreements has ended and direct contracts between social health insurance (SHI) schemes and pharmaceutical manufacturers introduced. For the first time SHIs are in a position to conduct concrete and individual talks with manufacturers and make use of their negotiating power in the form of invitations to tender.

As a result, the generics market has permanently changed in just a few years. In 2009, about 60 per cent of all packs sold in the generics market were subject to discount contracts between the SHIs and the manufacturers. At the same time, the invitations to tender enabled numerous companies to enter the German market, resulting in massive shifts in market share. Some of the world’s largest generics suppliers, including Teva, took the opportunity to multiply their market share overnight by profiting from the tenders issued by major health insurers.

Insurers, even in the area of patent-protected preparations and old originals, now take the opportunity to sign direct contracts. In addition to discounts, risk-sharing contracts are being created, such as those signed by Novartis with an SHI company for Aclasta.

Despite the state interventions already mentioned, the German market still has a high degree of flexibility with simple and fast access to the market for the pharmaceutical industry. Only in exceptional cases, such as vaccines, are separate recommendations required from the Vaccine Commission to guarantee eligibility for reimbursement by the SHI system. However, eligibility for reimbursement has been limited since 2004 by an efficacy assessment by the IQWiG (Institute for Quality and Efficiency in the Healthcare Sector).

If the expert appraisal of the IQWiG is negative, a further decision is required from the Joint Federal Committee (G-BA), as well as the final consent of the Federal Ministry of Health to withdraw products from eligibility for reimbursement by the SHI system. Substances for which the IQWiG has established no superior efficacy or requirement for further tests include, for example, shortand long-acting insulin analogues, glitazones or Atorvastatin. The reimbursement for the NMDA antagonist Azura, licensed for Alzheimer’s disease, is currently under discussion.

It is understandable that the IQWiG’s evaluations regularly come under attack not only from pharmaceutical companies, but also from patient groups whose therapies are suddenly refused. In the case of short-acting insulin analogues for diabetes mellitus type 1, the protest was effective, not with the authorities but with the pharmaceutical manufacturers, which have guaranteed reimbursement for human insulins through price concessions.

To date, no central pricing rules have been established for the introduction of an innovative pharmaceutical product; the initial pricing is established solely by the pharmaceutical companies. If a member of a health insurance scheme is prescribed a product, the health insurer is consequently obliged to reimburse the price indicated by the pharmaceutical manufacturers.

However, the recent Act to Reorganise the Pharmaceutical Market (AMNOG) – see more detail on the AMNOC Act and its ramifications on p40 – heralded the end of free drug pricing and established the fourth hurdle in the efficacy assessment of new therapies. From 2011, manufacturers will have to demonstrate the efficacy of new drugs in studies, for which they will be given one year after its introduction on
MARKET ACCESS

Germany has long been one of the most attractive markets for pharmaceutical companies due to its sheer size and its free drug pricing policy. Market access is granted immediately after marketing authorisation, and the inclusion of drugs into the Statutory Health Insurance (SHI) benefit catalogue is mandatory. But a variety of regulations has been introduced in the past few years that take effect after market access has been granted (see Figure 1, below). These range from jumbo group reference pricing to automatic generic substitution and rebate contracts.

Key stakeholders for market access are the Federal Joint Committee (G-BA) as well as the Institute for Quality and Effectiveness in Health Care (IQWiG) together with the strengthening role of the payers. A crucial development is the recently passed law on drug market restructuring, a paradigm shift that heralds the end of free pricing, to be replaced by central mandatory rebates.

Unlike in many other countries, once a prescription drug has been approved by the European Medicines Agency (EMA) or the Federal Institute for Drugs and Medical Devices (BfArM), marketing authorisation is granted immediately and reimbursement becomes mandatory for all SHIs. Less efficient drugs, such as cough and cold remedies, are not included in the SHI reimbursement scheme and are being moved into a quasi-negative list by the Ministry of Health (BMG).

In general, manufacturers are free to set prices for reimbursable prescription drugs, but the creation of internal reference price groups for pharmaceuticals has created substantial price pressures for all drugs subject to this regulation. The exclusion of drugs from the SHI reimbursement scheme or the inclusion into a reference price group can be initiated at any point and is not a mandatory process. These decisions are made by the G-BA, which consists of representatives from sick funds, social health insurance doctors, hospitals and patients and forms the most powerful institution in the German regulatory scene (Figure 2, over page).

FIGURE 1. GERMAN ACCESS CHALLENGES ALONG THE PRODUCT LIFE CYCLE
**FIGURE 2. REGULATORY PROCESS GERMANY (OUTPATIENT CARE)**

**FOCUS ON GERMANY**

In 1989, the internal reference price scheme for reimbursable drugs was introduced to curb pharmaceutical expenditure, which had been steadily rising. The aim of reference pricing is appealing: to pay a similar price for products that provide a similar benefit. The crucial question here is when and how drugs are put into a reference price group. In Germany, it is the G-BA that decides on the grouping of substances. Currently, drugs are assumed to be equivalent if they have either:

- Identical active ingredients or
- Pharmacologically or therapeutically comparable active ingredients or
- Therapeutically comparable effects.

The third category allows the G-BA to create ‘jumbo groups’ that contain many more drugs (including patent-protected drugs) than the molecule-based reference groups used by other countries.

After the grouping has been decided, the SHI establishes the actual reference price based on the difference between the cheapest and most expensive drugs. This price defines the reimbursement threshold for the group and the calculations are repeated annually. This means that if only one of the drugs in a jumbo reference group reaches the end of its patent protection, all products in the class are likely to face drastic price cuts. In theory, the principle of free pricing still applies but reference pricing creates massive price pressure, especially when cheap generics are part of the group, as the difference between the reference price and the actual price needs to be covered by the patient.

As referred to on p 34, the independent federal organisation for the evaluation of medical efficiency, quality and effectiveness (IQWiG) evaluates the effectiveness of drugs - either at the request of the G-BA or self-initiated - and prepares non-binding recommendations to the G-BA. IQWiG assessments serve as a basis for a number of important decisions:

- Whether to include a drug in a reference pricing group
- To define the SHI benefits catalogue
- And to amend existing treatment guidelines.

Initially, with regard to drugs IQWiG focused on benefit assessments only, but since 2007 the responsibilities were expanded and it may now also perform cost-benefit assessments. Until now, however, no cost-benefit assessments have been conducted, due to an ongoing debate around the chosen approach for economic evaluation which differs from established methodologies.

The IQWiG recently published its final method paper on the conductions of cost-benefit assessments. Unlike the method applied by UK’s cost-effectiveness assessor, the National Institute for Health and Clinical Excellence (NICE), the IQWiG paper does not define a cost-efficient threshold for the monetary value of a product’s benefit. Instead, it compares the cost-effectiveness of a new therapy with existing therapies, including generics. Consequently, it will be challenging for a drug to reach cost-effective status as defined by the IQWiG.

The SHI Competition Strengthening Act from 2007 enabled the SHI to make direct rebate contracts with pharmaceutical companies. These contracts have since become widespread between SHIs and generic companies, as their main purpose is to contain costs by promoting generic drug substitution wherever possible. The SHI puts time-limited contracts to tender based purely on price. Pharmacies then have to dispense the rebated drug to any of that insurer’s customers. Very few exceptions exist to this rule, one being the ‘aut idem’ rule whereby physicians can explicitly block substitutions by actually crossing out the ‘aut idem’ option. Depending on the size of the insurer (eg, AOK with about 35 per cent market share), this has a dramatic impact on the sales volumes of all other companies. This has led to a situation where generic manufacturers have entered into a fierce tender competition, granting rebates in a downward spiral of up to 90 per cent of the list price.

Beyond pure rebate contracts, more innovative approaches that also involve patent protected drugs have lately gained ground in the market. In order to avoid straight price cuts, to overcome reimbursement hurdles (eg when a drug is being put into a jumbo reference pricing group), or to keep the list price high in the German reference price market, some pharmaceutical compa-
PRICING AND REIMBURSEMENT CONTINUED

nies have started to introduce more sophisticated contracts, eg, by defining accompanying value-added programmes, performance guarantees or specifying complex risk-sharing agreements. A well-known example is the Novartis ‘no cure, no pay’ contract for an osteoporosis drug, whereby costs are refunded by the pharmaceutical company to the insurer if the treatment fails. Some companies are even pioneering ‘integrated care’ deals where not only the cost effectiveness of the drug is assessed but a holistic perspective is taken on all elements along the healthcare process. Contracts of this sort will play an increasing role in the German healthcare market, raising the bar significantly for all parties involved. At the moment, a wide variety of deals are being implemented in a trial and error fashion as both payers and pharmaceutical companies seek a competitive edge.

More than 90 per cent of the population is covered by statutory health insurance, which includes coverage for prescription drugs. If a prescription is dispensed by a pharmacy, the patient only pays a co-payment amount; the full price is charged from the pharmacy to the insurer. There are two types of co-payment. First, there is a fee that applies to all prescription drugs and ranges from €5 to €10. The second type is when a drug in a reference price group lies above the reference price; the difference is paid by the patient. If a drug in a reference price group is priced at least 30 per cent below the reference price, it is eligible to have the co-payment removed.

As explained previously, drug supply is mainly regulated through reference pricing and direct contracts. Physician drug demand, on the other hand, is regulated through prescription limits set on a regional basis. Individual physician prescription target volumes are calculated based on average prescribing cost per patient per year for each medical speciality. Physicians exceeding their targets incur audits and, in severe cases, have to pay a fine. These strict budgetary controls result in general practitioners prescribing cheaper drugs and generics where possible, but have displaced costs through early referrals to specialists or hospitals.

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GENERICS AND INNOVATIVE DRUGS

Germany is the third biggest pharmaceutical market in the world and still growing. Two-thirds of the overall spending is attributable to innovative drugs alone, which constitute only 30 per cent of all drugs on the German market. To cut these costs, health minister Philipp Roesler has instituted the new AMNOG law, the main thrust of which is a cost-benefit dossier for innovative drugs. This is the first time that prices of innovative drugs have been regulated in Germany.

Nearly two-thirds of all pharmaceuticals in Germany are generic drugs, making it the second largest generic market in the world – worth €5.3bn. While innovative drugs are considered price-boosters, generics were considered savers. But this has changed over the last few years, as healthcare costs have increased dramatically.

This is why there is a trend towards price regulations on generics that started with the introduction of rebate contracts. These were introduced in 2007 to enable SHIs to negotiate exclusive supply agreements with selected generic companies for their insurants. With the rebate contracts the focus was put on price, which had major effects on the generic market. Smaller companies suddenly grew in size, while big players with broad drug portfolios lost market share.

The implementation of the rebate contracts is reinforced by AMNOG, which facilitates the substitution of drugs. It expands the influence of the SHIs, but also introduces competition on brands by allowing patients to keep on taking drugs made by firms with whom their SHI has no rebate contract, but only if they pay for these upfront. These costs should then be refunded by their insurance provider – a fact that is heavily criticised by experts as unrealistic.

Despite all critical discussions about healthcare budgets and the fact that the development of new innovative drugs is very costly, Germany continues to be an important market for research-based pharmaceutical companies. In 2009, these companies spent more than €5bn on research and development. This was more than 10 per cent of the R&D spending of the German industry.

Political campaigns, such as the ‘Pharma-Initiative für Deutschland’, funded by the Ministry of Health (BMGF), are designed to boost pharmaceutical research. One of the effects of these efforts is a growing number of clinical trials that are conducted in Germany and the fact that there is an increasing number of companies running pharmaceutical research centres in the country. Twenty-five of the 45 members of the Association of Research-based Pharmaceutical Companies (VGA) run research laboratories; 38 are coordinating their clinical research activities in Germany and other countries.

In medical biotechnology, Germany has moved into a leading position. This trend is mainly due to the engagement of research-based pharmaceutical companies and the 360 biotechnology companies which brought to market a total of 141 approved genetically modified drugs. The total revenue adds up to €4.7bn.

Of the 44 pharmaceuticals launched in 2009 in Germany, 12 of them were biopharmaceuticals. The increasing relevance of biopharmaceuticals is also reflected in the data of a study recently presented by the association of research-based pharmaceutical companies (VFA) on their benefits, which records a total of 468 in clinical development in 2009, or a growth of about 12 per cent on 2008 figures.

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PIPELINE

A survey among the members of the Association of Research Pharmaceutical Manufacturers in 2009 revealed 442 potential new drugs which are in clinical phase I or II. Seventy per cent of these relate to the research into a new substance, 24 per cent are involved in the testing of a new galenic/administration form, and 6 per cent are involved in the investigation of extending the areas of indication.

The focus of 31 per cent of the research projects is on oncology, while, in positions two and three, 14 per cent and 13 per cent of the projects relate to infectious diseases and cardiovascular diseases, respectively. Chronic inflammatory diseases, which include rheumatoid arthritis, asthma, multiple sclerosis, Crohn’s disease, psoriasis and similar diseases, is covered by 10 per cent of the projects. COPD, diabetes mellitus type 2 and mental and neurodegenerative diseases are also strongly represented.

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PIPEDLINE CONTINUED

But projects to treat milder complaints or ‘lifestyle drugs’, eg, against menopausal symptoms, sexual disorders and incontinence, constitute only 3 per cent of the pipeline.

To be able to analyse individual responses of patients to future therapies to better effect, accompanying genetic studies are being conducted in 36 per cent of the development projects. This will allow future individualisation of the medicine based on genetic analyses, already common practice with some oncological therapies.

The focus of research among the major German companies can be seen in the areas of oncology, cardiovascular diseases, respiratory diseases and diabetes.

For example, in addition to its focus on endocrinology/women’s health and the areas of indication of COPD/pulmonary arterial hypertension (PAH), Bayer is also examining numerous substances in the field of oncology in phases I and II and is exploring indication extensions to cover Nexavar in the areas of intestinal and breast cancer.

Boehringer Ingelheim, in addition to entering the field of oncology, is also planning to license new substances for treating diabetes mellitus type 2. The diabetes pipeline includes the DPP-4-inhibitor linagliptin, in phase III, as well as an SGLT-2-inhibitor and a 11β-HSD1-inhibitor. Oncological research is concentrated on active ingredients for angiogenesis and signal transduction inhibition and on cell cycle kinase inhibitors.

Merck-Serono has over 30 projects in clinical development, focusing on neurology and inflammatory diseases. The research in inflammatory and autoimmune diseases is concentrated on proteins such as Atacicept or the fibroblast growth factor 18, which could be the first disease-modifying arthritis medicine.

COLLABORATIONS

With the end of the blockbuster business model, it is becoming apparent in Germany that the pharmaceutical industry is ready to treat new paths in the commercial exploitation of its products.

In a survey conducted by the Roland Berger Management Consultancy in 2008, 21 per cent of the managers from the pharmaceutical industry interviewed indicated that the biggest opportunities lay in the provision of services, while 20 per cent saw cooperation agreements as the greatest opportunity for growth.

Time will tell whether the forms of cooperation summarised under the term ‘collaborative healthcare’ will just be a short-term fad. What is certain, however, is that pharmaceutical manufacturers in Germany have already spent years intensively testing different possibilities of cooperation with both hospitals and medical service providers.

One area in which manufacturers are attempting to gain increasing access to the service sector is in so-called ‘integrated supply’, which the government has used to break up the highly developed sectoral organisation of the healthcare system. Innumerable local projects have been initiated which were extremely heterogeneous in terms of their degree of organisation and which presented the pharmaceutical industry with vastly different local market power. But some have succeeded in turning these structures to their advantage. For example, Janssen-Cilag, supplier of the schizophrenia drug Consta and a subsidiary of Johnson & Johnson, is supporting the treatment of schizophrenia patients as a partner in integrated care with the Lower Saxony General Health Insurance Scheme.

The direct contracts between pharmaceutical manufacturers and SHI schemes have given rise to a new form of market cooperation that goes beyond standard care based on collective agreements. The will to experiment with the newly acquired contracting freedom is recognisable on both sides. For years, for instance, there have been contracts which extend beyond the pure price component and now distribute risks involved in attaining therapeutic objectives. However, there is still a great deal of mistrust between the two contracting parties, and their negotiating power is subject to change, depending on the prevailing legal position.

It is doubtful whether, in such an unstable legal environment, a climate of trust can be built up which allows actual cooperation.

There is no doubt that the methods of commercialisation are changing dramatically. In the future, the prescribers will determine the economic success of a product far less than the payers in the form of social and private health insurance schemes.

However, it may be difficult to realise the potential of innovative contract models fully, as it is increasingly being questioned whether the paragraph which introduced direct contracts into German social law – § 130a SGB V – is sufficiently robust. At present, it seems difficult to imagine that pharmaceutical manufacturers will become service providers corresponding to doctors in the foreseeable future. Without a legal framework in which to provide services extending beyond its products, the industry will find itself in a grey area when it comes to incorporating service components into innovative contract models. The extent to which patient data can be divulged within the framework of selective contracts, or whether the permission of the patients is required for this, also remains to be clarified. The HWG (Medical Products Advertising Act) also represents an obstacle to supplying added-value services which are aimed directly at the patient, as it does not differentiate between neutral information and advertising.

Nevertheless, there are examples of very successful companies which have pioneered integration and found suitable ways of promoting diversification under company law. For example, Fresenius now covers services, clinical nutrition, medical engineering, pharmaceuticals and biotechnology by making additional purchases and interlinking all its divisions, and is well on its way to completing the transformation into a genuine integrated healthcare group.

It may be concluded that the legal environment in Germany currently fails to recognise the pharmaceutical industry as an equal partner in collaboration to allow its expansion into services.

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MARKETING

A comprehensive set of regulations and laws is shaping healthcare communication in Germany. The Heilmittelwerbegesetz (Law on Advertising in the Health Care System) legally limits product communication for prescription drugs to physicians and pharmacists only. Even non-prescription drugs are not free from regulations. Literally all the communication activities of pharmaceutical companies are legally considered advertising, which poses a major challenge to integrated marketing communication. Product-orientated campaigns targeting physicians need to be redefined if they are to be used to address patients.

Key messages and communication channels have to be adapted not only to
MARKETING CONTINUED

meet the target group’s needs but also to keep within legal requirements. Product names of prescription drugs cannot be mentioned to patients and public audiences. Only journalists have the right to publish the names of prescription drugs when reporting on news as they are acting under the German press law. This is why pharmaceutical product launches regularly include intensive media relations.

Many product campaigns targeted at physicians are often remodelled into public awareness campaigns for a specific indication or product-related unique selling point when patients need to be addressed. The connection between both campaigns is often secured by a variety of means. Subtly branded websites are established as communication platforms where physicians and patients meet. The branding often entails imagery or claims that visualise or address one particular feature or strength of the respective drug to ensure that the physician remembers the name of the drug if the patient mentions it.

With regard to integrated digital channels, social media is generally handled with caution by German pharmaceutical companies because of the difficult legal situation. Germany is not alone of course in this, and it is the lack of control that keeps companies away from engaging in social media, as they fear being held responsible not only for the content they are sharing but also for the comments their own contributions may generate.

Marketing in Germany also faces internal restrictions resulting from voluntary ethical guidelines of the association of research-based pharmaceutical companies (VFA) in Germany. These were put in place to provide guidance on the engagement of physicians in marketing activities, including participation in training or educational congresses. Many, but not all, pharmaceutical companies in Germany have approved these recommendations.

Another major challenge of integrated marketing is the highly differentiated medical community in Germany. The general practitioner (Hausarzt) is complemented by a variety of physicians specialising in different fields (Fachärzte). Plus, nearly every medical specialist is represented by at least one medical association or society, some of them only for hospital clinicians (Kliniker) or physicians in private practices (Niedergelassene). This diversity has to be taken into consideration when setting up an integrated campaign, positioning a brand or a topic. The different interests and informational needs are reflected by a huge number of specialised medical trade media providing news and views for nearly every medical target group. There are at least 35 medical journals on neurology alone. Further, each group of healthcare professionals, such as midwives, has its own range of special interest magazines. The leading German physician’s magazine Deutsches Ärzteblatt recently listed a total of more than 1,100 medical journals in Germany.

The German public media landscape is also rich, with more than 1,690 newspapers, 973 journals, 245 radio stations and 53 TV stations, many of which have healthcare-related categories or broadcasts. The increasing number of free healthcare journals being distributed in pharmacies and private practices reflects the growing public interest in health topics. The waiting areas of private practices have become information channels offering magazines, brochures and information leaflets from companies and associations directly to the patients. Awareness campaigns often use this route for patient education and training.

The internet is the leading source of health information for the public. Various healthcare portals provide news and information, offer expert views or provide general counsel on the most common diseases. Other public sources of information are the numerous websites of patient groups, medical associations and the industry, providing background information or offering the chance to contact other patients.

For economic reasons, new target groups have come into focus in recent years. Being confronted with cost-benefit discussions, pharmaceutical companies are forced to communicate with payers and other stakeholders much earlier than they once did. Health policy-brow-beats the pharmaceutical industry by regularly introducing new regulations and requirements. For the approval of a new drug the manufacturer not only needs to prove efficacy, safety and tolerance, but also has to provide a cost-benefit evaluation. This is why integrated product campaigns have to start much earlier in the pre-launch phase. This is vital not only to get the various target groups on board in time but also to secure a proper messaging that reflects the brand’s essence.

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DIGITAL MARKETING

In Spring 2010, 49 million Germans – representing 69.4 per cent of the total population – were surfing the web at least occasionally, as the recently published ARD ZDF online study revealed. More than three-quarters of these online users were using the internet at least once a day, which reflects the medium’s importance. In Germany, it is clearly the single most important source of information, as demonstrated in the recently published 2010 Digital Influence Index (DII), conducted by Fleishman-Hillard International Communications in conjunction with Harris Interactive.

However, despite the fact that the internet is by far the most influential media channel, when it comes to driving consumer decisions about products and services, marketers worldwide have yet to capitalise on that influence. This key finding of the 2010 DII is completely true for Germany in general and for the healthcare sector in particular. Internet surfers are primarily using search engines, user comments and product/price comparison sites as the main sources for information on health. Social media is of major interest when looking for comments and recommendations on physicians, dentists or advocacy groups.

In terms of marketing, the most interesting results of the study were the great importance of company and product websites, serving as the main sources of information for patients, and the fact that online banners are playing a minor role for health-related decisions in Germany. The importance of industry information relates well with the rich portfolio of product and disease-related websites of pharmaceutical companies. The minor role of banner ads may be due to the fact that digital healthcare marketing is still not very common in Germany. It plays a minor role in integrated healthcare communication, as reflected by the fact that online activities such as the ‘Am I number 12?’ awareness campaign on hepatitis (www.binichdienummer12.de) are still rare in Germany. Most digital communication activities are to present and distribute information about non-prescriptive products or diseases. Dialogue with patients is not yet an option, due to legal issues.

Even in scientific communication, digital platforms are still focusing on informing and educating experts on drugs, diagnosis and treatment
of disease. Various pharmaceutical companies run online platforms for professional training and education, some of them allow discussions between their members. But classic websites are still considered the gold standard in digital healthcare communication.

Social media is quite popular in Germany generally. More than half of all German organisations, including companies, state and non-governmental organisations, are engaging in Facebook, Twitter and professional platforms like Xing and LinkedIn. These channels are commonly used by the medical community in Germany. Healthcare professionals’ portals, like facharzt.de, are well established in the community and are commonly frequented by professionals to exchange information and to discuss news and issues. Despite these trends, pharmaceutical companies in Germany are still hesitant to engage with these professional platforms due to legal considerations. It is the lack of control on what is posted and commented on that scares companies away, as healthcare communication is strongly influenced by the regulations of the law on advertising in the healthcare system. This is why most still focus on expert hotlines, online training and personal communication to engage with their professional audiences.

Healthcare blogs are not common in Germany with just a few bloggers addressing health topics. Health-related issues are mainly discussed in digital health forums. Most of them are open to the public and are maintained by health platforms or independent authors. Pharmaceutical companies have not yet started to launch such forums. But a few companies have started to engage with bloggers and health-related social media channels by distributing social media releases designed to engage with bloggers, online journalists and other stakeholders by sharing material that could be used on authors’ websites, blogs or pages.

In lay communication, open dialogue is not yet an option. Most of the pharmaceutical companies in Germany have not even started to engage in Web 2.0. But this might well change quite soon.

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2010 AMNOG ACT

As mentioned earlier, the 2010 Gesetz zur Neuordnung des Arzneimittelmarktes, (AMNOG) Act was designed to restructure the drug market and had a special focus on price negotiations for patent protected drugs. It introduced a price formulation for new drugs based on the concept of additional therapeutic value. While prescription drugs still move immediately into the SHI benefits catalogue after marketing authorisation, there is now a mandatory rapid assessment (within three months) by the G-BA to determine a drug’s added value.

Three to six months after marketing approval, the pharmaceutical company is granted a G-BA hearing where it can present arguments to support this added value. For products with an acknowledged added value, the company must negotiate a central rebate with the SHI head association. If no agreement can be reached, an arbitration board will establish a price aligned with the European average.

The European average price is likely to be established once a product’s prices have been announced in all reference price countries. Products with no acknowledged added value are directly categorised into existing reference price groups. If there is no way to build a reference price group for a therapy, a maximum reimbursement price will be set at the current annual cost of a comparable therapy.

If the pharmaceutical company or the SHI head association do not agree with the price resulting from the arbitration board they can request a cost-benefit assessment by IQWiG. The outcome of the assessment could then result in a price change.

Also under the new act, it remains beneficial not to be reference priced. For this to happen, the phase III trial design must comply with G-BA/IQWiG standards. The act allows a session for the G-BA to consult with the pharmaceutical company on how to best set up the clinical trial phase III study. While this approach opens up a dialogue between the two parties, it also results in a binding agreement on the study design and therefore does not leave much flexibility for the company.

Depending on the added value of a new drug, these scenarios are conceivable:

- A ‘real innovation’ will be classified as added value. The pharmaceutical company will be able to negotiate a central rebate with the SHI. As a breakthrough innovation, the product will not need to secure its market share by entering individual contracts with insurers. Only once the drug loses its exclusivity will innovative contracting models need to be evaluated to secure a reasonable share of the market.
- It will be difficult to convince the G-BA of the added value of an ‘incremental value add product’, in which case, pharmaceutical companies need to present a solid argument for why the product adds substantial value at the G-BA hearing. If the G-BA does not acknowledge the product’s added value, it will be reference priced. To keep the price cut as small as possible, the company should try to argue for a reference price group that does not include generics. Cooperation contracts need to be taken into consideration to secure a significant market share.
- ‘Me too’ products will inevitably be reference priced. The pharmaceutical company must demonstrate why the product should be categorised into a favourable reference price group. If the therapeutic area is on the strategic agenda of insurers, a cooperation contract should be aimed for. Otherwise, simple rebate contracts may be the only way to secure market share. Depending on the COGS and European average price, it might have to be considered not to launch the product on the German market as it is very likely that a downward pressure is created.

In addition, the cost-benefit assessment that a pharmaceutical company can finally request does not constitute a realistic chance for a product’s case for price correction. As IQWiG compares a drug’s cost-effectiveness with the cost-effectiveness of similar therapies including generics, a price above the European average will hardly be achievable. It is, therefore, highly unlikely that IQWiG will conduct many cost-benefit assessments. Hence from a HTA sophistication perspective, the new pricing reform means a reverse development.

In summary, there will be four levers that pharmaceutical companies need to understand and be proficient in to ensure a decent reimbursement level in the German healthcare market:

- Phase III study design
- Supporting arguments for a product’s value add at the G-BA hearing
- Arguments for grouping into a favourable reference price group at G-BA hearing
- Individual contracts.

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COUNTERFEITING

The supply chain in the German pharmaceutical industry is regarded as extremely reliable. Even parallel importers are subject to similar quality requirements to those imposed on pharmaceutical manufacturers; they require their own manufacturer’s licence and are subject to strict regulations for control and monitoring of the products. According to Federal Criminal Police data, only 49 cases of drug counterfeiting in the legal supply chain have been recorded since 1996.

But there is no doubt that drug counterfeiting is on the increase in the EU, and hence also in Germany, despite poor data availability. According to the European Commission, customs officials in the EU confiscated over 11 million drugs in 2009 – 10 per cent of all products confiscated. The number of counterfeit drugs rose in 2009 by just under 30 per cent compared to the previous year, after an increase of 57 per cent in 2008.

The highest proportion of drug counterfeits originates from the United Arab Emirates (73.7 per cent), followed by India (22.6 per cent), China and Syria (1.4 and 1.3 per cent, respectively). A total of 11.5 million packs of drugs was confiscated; only cigarettes, tobacco products and brand products were confiscated more frequently than drugs.

It is no longer merely lifestyle preparations and products for doping abuse that are being introduced as counterfeits, but increasingly drugs from classical substance classes. It is not only cholesterol and blood pressure reducers and agents against osteoporosis, but also analgesics and antibiotic preparations that have become victims of counterfeiting. High margins on HIV and cancer drugs make them particularly interesting to the counterfeiters.

In this case, the purchasers are no longer the patients, but the administering medical practices and clinics, as well as the dispensing pharmacists. To place counterfeits successfully on the market in these areas requires either a detailed knowledge of the supply and documentation structures and highly developed logistics, or accomplices who have access to the legal system and are able to smuggle counterfeits in with the legal circulation of goods. Investigations were begun in August 2010 into the activities of a dozen pharmacists in northern Germany suspected of having mixed licensed with unlicensed cytostatics and then marketing them.

Websites operated abroad provide a gateway for counterfeit products. Dealers ship their products without a regular prescription or issue a prescription on the basis of an online questionnaire. The products are hardly ever supplied with the original pack and information on their use. Test purchases on such sites revealed half of the products supplied were counterfeit. The legal mail order trade in Germany, through licensed pharmacies, is increasingly being criticised because of mail order dealers operating illegally. So there have been several attempts to abolish the mail order trade as the consumer is unable to distinguish between legal and illegal dealers. But, so far, the industry has successfully managed to defend itself.

Pilot schemes are testing methods to prevent counterfeiters coming on to the market. Recently, there has been a tendency to copy 2D data matrix codes as an end-to-end authentication method versus radio frequency identification. Although the RadioPharm project, which began in 2008, has passed a proof-of-principle test, Aegate has been able to secure a partnership with the German Association of Pharmacists (ABDA) and has the support of one of the major members of the German Pharmaceutical Association (BPI). Aegate’s system, based on the data matrix code, enables comprehensive point-of-dispensing verification in the pharmacy.

Internationally, national associations and the European Federation of Pharmaceutical Industries and Associations (EFPIA) are trying to develop a pan-European approach to anti-counterfeit measures.

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