FOCUS ON: **Market Access & HTA**

A Look at Reimbursement Issues in Germany

By Bernd Brüggenjürgen, MD, MPH, Managing Partner, Alpha Care GmbH, Cooperating Partner of UBC, and Head of the Health Economics Chair at Steinbeis University Berlin, Germany. Prof. Dr. Brüggenjürgen is an expert on the German health care system.

The German pharmaceutical market still looks inviting to drug manufacturers. Germany has one of the highest levels of health care spending in the world and has the largest pharmaceutical market in Europe (and the third-largest worldwide). In 2009, drug spending increased by 5.3% compared to 2008, which is about 1.5 billion-Euro.[1] Drug manufacturers also enjoy a great degree of freedom in setting pharmaceutical prices, which are among the highest in Europe. However, pharmaceutical companies seeking to do business in Germany must contend with many cost-containment measures. These include prescribing guidelines, patient copayments, reference pricing, a negative list of drugs excluded from reimbursement, generic substitution, and parallel import dispensing targets. Moreover, the adoption of cost-effectiveness as a requirement for reimbursement is due to be implemented for selected substances launching in the coming year. While generics' pricing is mostly under control, patented drugs are the main growth driver, which explains why current reform trends focus on branded drugs.

Germany is Europe's biggest pharmaceutical market, worth more than 30 billion Euro annually, and continues to be a major influence in drug pricing overall for the European Union.

Most Germans (about 90%) rely on the country's Gesetzliche Krankenversicherung (GKV; statutory health insurance—SHI) for their health care. Pharmaceuticals are the third-largest area of GKV expenditure after hospitalisation and treatment by physicians. As in other countries, the growth of the pharmaceutical market is a contentious issue in Germany. Since the late 1980s, successive governments have imposed a wide range of cost-containment measures. However, some observers believe that the German health care system has not exploited the full potential of these measures.

Hospital inpatient services are reimbursed through a system of diagnosis related groups (German DRG—"G-DRG"). For ambulatory care provided to SHI members, physicians are reimbursed on a mixture of pre-paid capitation, treatment lumps sums, and fee-for-service according to a point-based doctors' fee scale, the so-called German Uniform Evaluation Standard (Einheitlicher Bewertungsmassstab—EBM 2009). Each physician has a "capitations of service" volume per quarter, which varies regionally, between specialties and morbidity of patients.

A central body for market access is the G-BA: The Joint Federal Committee on Healthcare (Gemeinsamer Bundesausschuss) which is the central agency for reimbursement decisions in Germany. Its main task is to determine and communicate which outpatient or inpatient therapies and drugs are part of the benefits catalogue of the SHI. The G-BA is authorized by law to issue directives, which are binding, on sickness funds, the insured population, panel physicians, and hospitals. In the event that the G-BA is indecisive on whether, for example, certain therapeutic strategies in indications would work, the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen—"IQWiG") could be requested to perform a health technology assessment (HTA) process.

IQWiG is similar to the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom and is an independent, scientific institute that provides technology assessments, with the major difference being that NICE offers guidance on treatments, while IQWiG only assesses the health technology without any further guidance

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and reimbursement decision on treatment. Their primary task is to assess (not to appraise) the benefit of drugs and therapies, as well as cost analyses for drugs. The IQWiG's evaluation frame is defined by one of its own method papers,[2] as well as by the G-BA. The usefulness of a method generally has to be proven with the aid of studies satisfying Evidence Stage I, measuring patient-related outcomes (e.g., mortality, morbidity, quality of life). If no studies of this quality are available, the cost-benefit analysis can be based on high-quality studies of lower evidence stages. However, the recognition of the medical usefulness of a method on the basis of lower evidence stage studies requires special justification, which needs to be increasingly solid the more a study deviates from Evidence Stage I. The interaction between G-BA and IQWiG regarding reimbursement decisions is quite complex. G-BA can evaluate treatments by itself through subcommittees, working groups, and expert hearings.

The reference pricing system, which covers approximately 60% of medicines reimbursed under the GKV public insurance system, will be maintained with drugs priced at least 30% below the reference price being eligible to have patient co-payments removed. However, drugs included in the reference pricing system will be increasingly targeted by negotiating further discounted contracts. While this will obtain considerable savings for Germany's statutory health insurance funds, patients will still have the possibility to choose non-discounted medicines in exchange for additional co-payments.

A rebate system is also in place in Germany. Collective rebates comprise a manufacturer's discount (6%—if not reference price regulated), a pharmacy discount (€2.30 per pack), and a generics discount (10% since 4 January, 2006 onward). In addition, individual rebates (Rabattverträge §130a[3]) are increasing considerably, where SHI-funds are allowed to contract directly with pharmacies for selecting the generic to be substituted, and where SHI-funds are in a position to reduce or to lift the co-payments for their insurees.

Current ongoing political changes include the following:

- **Assessing value of new drugs:** The G-BA and IQWiG may be the ones running these analyses, however, recent information indicates that the Federal Ministry of Health is setting up the list of evaluation parameters, hence steering the process, supported by its own benefit assessment studies. Drugs without added value compared with alternative treatments will be directly included in Germany's reference pricing system.
- **Maintaining free market access for innovative products:** Since Germany is a reference market for drug prices in many European Union (EU) member states, manufacturers have been reluctant to reduce their prices in Germany. To be rebated, prices of those drugs with added value will be negotiated between the GKV and pharmaceutical companies. Official list prices will be kept.
- **Introducing the obligation for manufacturers to negotiate prices with Germany's SHI within the first year after marketing approval:** Prices negotiated within one year of marketing approval will take effect for all statutory health insurances funds in Germany. If no agreement is concluded within three months of benefit assessment, the GKV will set a price based on international reference prices. Pharmaceutical companies might set a price unilaterally if agreement with the insurers has not been reached after 15 months.
- **A further extension of individual contract negotiations according to §130a:**[3] Individual contracting so far could be based on quantitative elements like amount- dependent rebates or compensations when exaggerating targets. In addition, a qualitative element has been introduced, which allows the integration of the development of contracts based on therapy outcomes.

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pricing overall for the European Union. While cost-containment strategies continue to be evaluated and implemented, the evidence needed for market access also continues to be reviewed and updated so all relevant parties are considered in the final decisions and policies.

For more information, please email evidence@unitedbiosource.com.

References

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[3] http://www.kbv.de/12909.html