



An Overview of Pharmaceutical Market Authorization Procedures, Current Trends and Opportunities in the Reimbursement Scheme

Home to the world's third largest market for pharmaceuticals, a highly productive R&D scene, and excellently qualified people ready to tackle new markets, huge opportunities await foreign pharma investors in Germany.

This brochure gives a short overview of the pharmaceutical approval requirements and reimbursement system within Germany in order to provide foreign investors with a better understanding of the German health care and regulatory systems.

competent authorities of the individual EU member states to ensure safety, efficacy, and quality before they can be sold commercially. Marketing authorization regulations are harmonized in all EU member states, and are similar to those rules established by the Food and Drug Administration (FDA) in the United States. Centralized marketing authorization is required for almost all innovative pharmaceuticals. This authorization is granted by the European Commission based on a positive EMEA appraisal of the respective pharmaceutical. This centralized marketing

recognition procedure (MRP) or purely national procedures which all result in national authorizations. The competent authorities for granting marketing authorizations in Germany are the *Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM – "Federal Institute for Drugs and Medical Devices") and the Paul Ehrlich-Institut (PEI). Approval from the relevant competent authorities is only valid in the German market. National authorizations can be used as a basis for the MRP to ensure easier access to other European countries. In 2004 the DCP was introduced – in addition to CP and MRP. This new procedure has opened up the possibility of parallel applications within individual EU member states.



How to Obtain Market Authorization for a Pharmaceutical?

Pharmaceuticals (or "medicinal products" according to EU legislative classification) require marketing authorization from the European Commission/European Medicines Agency (EMA) or the nationally

authorization is valid in all EU member states. Since the most recent review of EU law it has become possible for generics to use the centralized procedure (CP), but most generic pharmaceuticals are authorized through the decentralized (DCP) or the mutual

How Do Pharmaceutical Entrepreneurs Receive Money for Their Pharmaceuticals?

In general, manufacturers are free to set ex-factory prices. However in practice, reimbursement reference prices restrict the free setting of prices. For prescription pharmaceuticals and reimbursed non-prescription pharmaceuticals, the margins for the wholesalers and pharmacists are regulated by pharmaceutical price ordinance. Non-prescription pharmaceuticals are purchased by patients without prescription (self-medication/over-the-counter - OTC).



Prescription Pharmaceuticals in Germany

According to the *Sozialgesetzbuch* ("Social Security Code"), manufacturers and pharmacists have to grant obligatory rebates for prescription pharmaceuticals to the statutory health insurance system.

German social insurance is a statutory insurance system which plays a predominant role in Germany's overall social security. The German wage-based social health insurance (SHI) system insures approximately 90 percent of the German population. Since 2009 members of statutory health insurance pay the same wage-based contribution rate, which is set by the government. SHI contributions are paid by employees and employers. The insured can choose their SHI, and can additionally register for supplementary insurance tariffs. Ten percent of the German population participates in the private health insurance system. All residents must be registered in either a private or statutory health insurance scheme.

In-Patient Care

The rules governing the reimbursement system for in-patient care are different, as they cover the full cost of pharmaceuticals as part of the universal coverage package. Each hospital draws up a list of included pharmaceuticals and contract prices with the supplier. Hospital charges are based on the DRG system (diagnosis-related groups); a pricing system originally developed by the Medicare administration in the US. DRG-based prices are all-inclusive for the in-patient hospital stay and also cover pharmaceuticals. Very expensive pharmaceuticals are covered by supplements to the DRG, and are billed separately to the health plan issued by the hospital. The DRG and its corresponding surcharges are updated regularly.

Out-Patient Care

For out-patient care, the pharmaceutical price ordinance defines the surcharge for wholesalers and pharmacies. The ordinance is set by the federal government, so that a specific package is sold in all pharmacies at the same price.

The SHI has to offer a universal benefit package that covers all prescription-only pharmaceuticals prescribed by physicians in out-patient care. Some pharmaceuticals are excluded from this coverage, in particular lifestyle pharmaceuticals and most OTC pharmaceuticals. Since 2004, non-prescription pharmaceuticals – except those administered to children – are no longer reimbursable. An exemption list

also exists for special diseases. Moreover, pharmaceutical guidelines and recommendations exist for some reimbursable pharmaceuticals.

The SHI pays the price for pharmaceuticals prescribed in out-patient care directly to the pharmacies. The reimbursement of generics and some patent-protected pharmaceuticals in out-patient care is limited by reference prices. The *Gemeinsamer Bundesausschuss* (G-BA "Federal Joint Committee"), a self-governing body of the German health care system, determines the groups of pharmaceuticals reference prices are to be defined for. Reference prices must not be imposed upon patented pharmaceuticals with therapeutic advantages. However, this criterion



has not been applied to date. In general, groups should guarantee therapeutic choices as well as grant reasonable and necessary prescribing alternatives.

There are three classes in the reference pricing system.

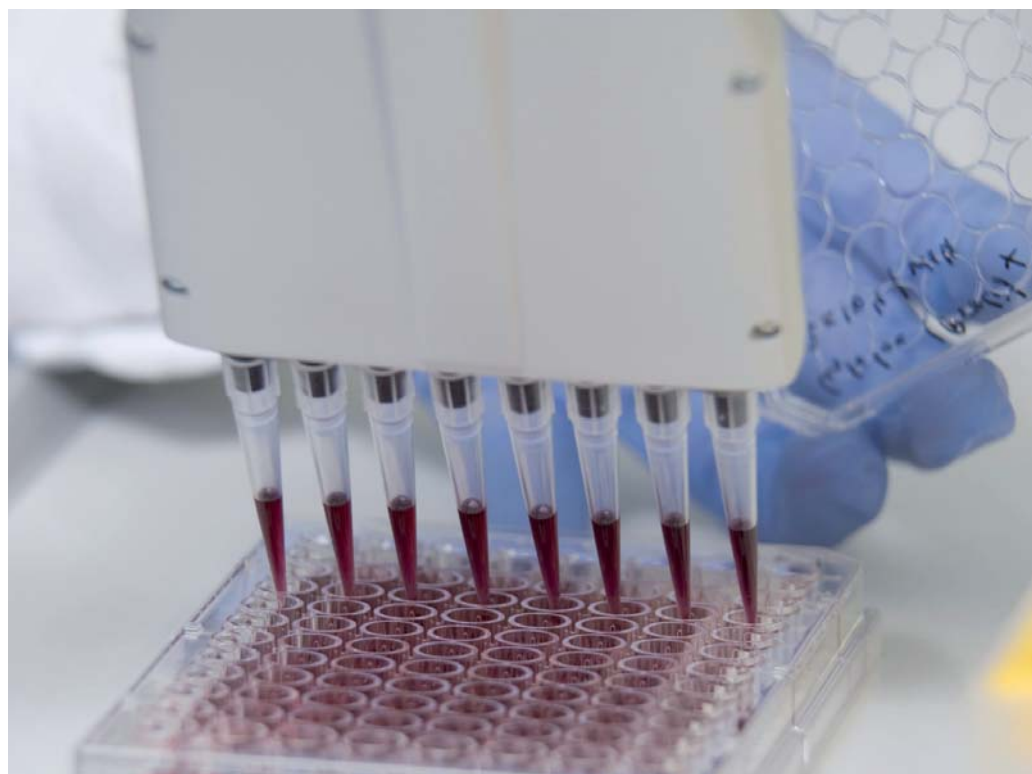
Class I: pharmaceuticals with identical active substances;

Class II: pharmaceuticals with active substances that are pharmacologically and therapeutically equivalent, especially products with comparable chemical components;

Class III: pharmaceuticals of equivalent therapeutic effect, especially combination products.

Where the price is higher than the reference price, the patient has to pay the additional cost. Reference prices are established for more than 70 percent of prescribed pharmaceuticals in out-patient care, of which, over 90 percent do not cost more than the reference price.

In addition, each health insurer may negotiate discounts on prices for pharmaceuticals used in out-patient care with pharmaceutical companies. Where such a contract has been entered into, the pharmacy is obliged to dispense the contracted generic pharmaceutical to the patient registered in the respective health plan. Contracts are also possible for patent-protected pharmaceuticals. SHI can offer incentives to physicians to follow the insurance provider's pharmaceutical list. The insured are obligated to contribute to the costs of their pharmaceuticals via co-payments. These co-payments for pharmaceuticals are low and amount to 10 percent of the pharmacy price - a minimum of EUR 5 per package, but not more than EUR 10. Under some specific conditions, low-priced pharmaceuticals can be exempted from co-



payments. Health insurers may also exempt contracted pharmaceuticals from co-payments, or if the price is at least 30 percent below the reference price.

The prescription of Rx pharmaceuticals by physicians is restricted by contracts between the umbrella organizations of the health insurance providers (*Spitzenverband Bund der Krankenkassen* - "Central Federal Association of Health Insurance Funds") and the physicians (*Kassenärztliche Bundesvereinigung* - "National Association of Statutory Health Insurance Physicians").

These contracts limit prescriptions to a maximum average total value of prescriptions per patient. However, patient access to high-cost pharmaceuticals necessary for medical reasons is guaranteed by law to ensure that the patient obtains the necessary pharmaceuticals required for medical recovery. These costs are

exempted from the prescription limits. Pharmaceutical manufacturers have to pay obligatory rebates to the SHI system. In general, pharmaceuticals outside the reference price system pay six percent on the manufacturer's price. If a pharmaceutical is off patent, and alternatives containing the same active ingredients exist, then the rebate is 10 percent. Drugs under reference price system can avoid the rebate if they decrease the price by at least 30 percent below the reference price. Products without reference price and off patent with existing alternatives pay 16 percent rebate to SHI.

Evaluation of Drug Benefits

If a pharmaceutical is less effective or more expensive than other therapies, prescription may then be restricted to certain indications or groups of patients according to the guidelines laid out. These guidelines are established by the G-BA, which is an umbrella organization of health insurers and health care providers. The guidelines are based on medical evaluations delivered by the G-BA's scientific institute, the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG – "German Institute for Quality and Efficiency in Health Care"). This institute can also work on pharmaceutical cost-benefit analyses if the G-BA mandates it to do so. When an innovative pharmaceutical reaches the market for the first time, it can be prescribed immediately to patients registered in the SHI. The question as to whether a new pharmaceutical is more effective than an existing pharmaceutical is not a hindrance to a physician, as the physician can prescribe the pharmaceutical until its benefits have been evaluated.

New Instruments

For some pharmaceuticals a second opinion procedure is being introduced.



Notes

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