



Medical Devices

CE Marking and Reimbursement in Germany

Germany is an excellent investment destination for the world's leading manufacturers of medical devices. This document explains the regulatory requirements to bring a medical device to the European market and gives an overview of the German reimbursement scheme for medical devices.

Medical Device Certification: The CE Marking

Any medical device intended for the German market must bear a CE marking before it can be sold or put into service. The CE marking is a mandatory conformity mark affixed to certain products intended for sale within the European Economic Area (EEA) to indicate conformity with the essential health and safety requirements set out in European directives.

CE marking is the declaration by the manufacturer (and acceptance by a European authorized conformity assessment body) that a product complies with relevant directives. The fulfillment of essential and other legal requirements is determined in a formal conformity assessment procedure (*Medizinproduktegesetz* or MPG – “Law on Medical Devices”). Medical devices with the exception of in vitro diagnostic medical devices and active implantable medical devices are divided into four classes (I, IIa, IIb, and III) according to European directives. EU Commission medical device classification explanations and examples guidelines can be found online (http://ec.europa.eu/enterprise/medical_devices/).

Depending on the class of product, conformity can be proven by the manufacturer or with the involvement of a notified body. Such intervention is necessary for all active implants (in accordance with Council Directive 90/385/EEC), for in vitro diagnostic medical devices (in accordance with Annex II of Council Directive 98/79/EC or for self-administration), as well as for other medical devices of classes III, IIb, or IIa and class I products which are placed on the market in a sterile condition or which have a measuring function.

Medical devices with minimal risk can take advantage of the self-certification process whereby the manufacturer provides a declaration of conformity before affixing the CE marking to the product. Medical devices with greater risk require voluntary certification by a notified body (a list of notified bodies can be found at the German Institute of Medical Documentation and Information website: <http://www.dimdi.de/static/en/mpg/benanntestellen/index.htm>). Other devices must be examined by or on behalf of an external inspection organization or notified body within the EEA. CE marking provides medical device and technology market access to EEA 30 and MRA countries with a population of almost 500 million. The creation of a single Europe-wide system of health and safety conformity classification promotes quick design and manufacture turnaround times for swift European market entry.

The manufacturer or authorized representative is responsible for the first placing of new medical devices on the market. The medical device importer is responsible in cases where the manufacturer's registered place of business is outside the EEA and an authorized representative has not been designated (or if medical devices are not being imported into the EEA by the authorized representative).

Medical Device Reimbursement

Germany operates a dual health system with statutory health insurance (SHI) and private health insurance. All German residents are obliged to take either statutory health insurance or private health insurance. Almost 90 percent of the population is insured by the SHI system, with the remaining 10 percent of the population opting for private health insurance.

The SHI provides universal health benefits for all according to the health care provisions approved by the Federal Joint Committee (the paramount decision-making body within the self-governing German health care system). The next section discusses only the reimbursement of medical devices by the statutory health insurance system.

The reimbursement system is divided into two types of reimbursement: the reimbursement of medical devices dispensed in the form of “in-patient” care (in hospitals and other health institutions); and the dispensing of medical devices prescribed by physicians through pharmacies and retail outlets to patients who are not receiving hospital care (“out-patient” care).

In-Patient Care

Germany operates an acute “in-patient” reimbursement system based on diagnosis related groups (DRG).

The reimbursement of “in-patient” care medical devices dispensed to hospitalized patients is regulated by the diagnosis related group (DRG) system. The introduction of this system in 2003 also saw the introduction of a special reimbursement process specifically developed for new health technologies. DRGs list which treatments (including medical devices) can be given to patients according to individual diagnosis. The hospital receives a fixed amount that is set-up by the DRG system for the entire treatment of the patient. The DRG system does not set prices for the medical devices which are used for the treatment of the specific diagnosis covered by the DRG. Medical device prices are negotiated between the hospital and the respective medical device manufacturer according to the specific device used to treat the patient subject to the relevant DRG.

The DRG system is open to new forms of treatment which are not listed in the current DRG scheme. This is important for novel medical devices, as the existing DRG might not foresee treatment using a novel medical device. There are several

ways to include novel medical devices in the reimbursement scheme for hospitals to ensure that new medical devices can be used in hospitals without becoming bogged down in red tape. However, the application for the inclusion of a medical device as a new treatment should be filed as soon as possible, as the new treatment needs to be assessed prior to its embedding in a DRG. This assessment can be time-consuming and take up to three years depending on the treatment at stake. Nevertheless, the use of any novel technology (stem cells, for instance) is not restricted unless a negative decision regarding its efficacy has been made by the competent authorities.

Out-Patient Care

Also called “ambulatory care,” out-patient care refers to diagnosis, observation, treatment, and rehabilitation provided on a non-hospitalized out-patient basis.

The reimbursement of all physician-performed out-patient care treatments is subject to a schedule (“Standardized Assessment Factor”) which determines the content of all billable benefits. Benefits not listed in this schedule cannot be billed to the statutory health insurance system by health care professionals. The Federal Joint Committee has to determine whether a specific benefit is billable to the SHI prior to the benefit being discharged. For this reason, treatments which involve the use of a novel medical device but which are not listed in the “Standardized Assessment Factor” schedule cannot be billed to the SHI.

Therapeutic Appliance Schedule

Statutory health insurance fund reimbursable medical products must satisfy a number of minimum

standards in order to be included in the *Hilfsmittelverzeichnis* (“Therapeutic Appliance Schedule”) of approved medical devices. Under the direction of the GKV (the central SHI association), umbrella organizations of the different statutory health insurance funds compile a therapeutic appliance schedule as well as a separate appendix of care products. Medical devices included in this directory can then in principle be prescribed, with the cost being borne by the statutory health insurance funds.

In order to be included in the therapeutic appliance schedule, all medical devices must bear the CE marking. Additional quality requirements can also be specified. These conditions apply also to the *Pflegemittelverzeichnis* (“Care Product Schedule”) for medical devices used in nursing. All applications proposing the admission of CE-certified medical devices and care products must be submitted to the GKV umbrella organization. Applicants must provide information supporting product functional suitability, safety, quality, and – subject to requirement – medical or nursing care benefits. The GKV informs applicants of the application decision in writing.

Products which satisfy reimbursement list criteria are listed with reference to both the responsible manufacturer and specific construction features. Health insurance providers are obliged to provide indemnification for medical devices included in the reimbursement list. The statutory health fund provider has to evaluate in each case whether a duty of provision exists. This also applies to those products for which no product group classification or individual product listing is available. It is

necessary to submit an application for such products that they might be considered for inclusion in the therapeutic appliance schedule once corresponding product groups have been evaluated.

The complete procedure (from application to acceptance of a medical product as a recognized therapeutic aid) is regulated by a number of legal provisions discussed in the *Strukturgegebenheiten und Prozessabläufe im Hilfsmittel- und Pflegehilfsmittelbereich* ("Structural Conditions and Process Procedure in the Therapeutic Aid and Nursing Aid Sector") handbook available to download at the GKV website.

A package of reforms to the Act on Medical Devices is helping reduce bureaucracy and fostering increased transparency and deregulation within the reimbursement process.

Therapeutic Appliance Guidelines

The "Therapeutic Appliance Guidelines" contain general prescription principles as well as special provisions pertaining to visual and hearing aids. These guidelines ensure that the insured receive adequate, appropriate, and cost-efficient medical provision. They decide to which degree doctors and health insurance funds can prescribe and reimburse therapeutic aids to the insured patient. Basic commodities and items of everyday use may not be prescribed by the statutory health insurance system.

Fixed Amount Groups

So-called "fixed amount groups" exist for specific, easy-to-compare products. A maximum payable sum to which these aids can be reimbursed is set for these therapeutic appliances.

Because many therapeutic aids are nevertheless not comparable, the fixed amount groups concern only the following: orthotics, hearing aids, incontinence aids, compression therapy aids, visual aids, and ostomy aids.

Advantages and Opportunities

The International Medical Technologies Market

The global market for medical technologies in 2008 reached the EUR 220 billion mark. The European market is the second largest market in the world after the US market (with revenue of EUR 65 billion compared to US turnover of EUR 85 billion). Germany is the third largest individual market after the US and Japan (EUR 25 billion), and Europe's largest individual market by some distance. The German medical technologies market is twice as large as that of France, and three times the size of the markets of Italy and the United Kingdom respectively.

Germany – Unmatched Investment Opportunities

Germany is a key player in the world's medical devices markets. Health care spending in the medical devices sector alone accounts for some EUR 22 billion of the German health economy (overall health economy sector sales revenue development for 2007 was 4.6 percent – with innovative sectors able to record double-digit growth rates). Furthermore, the health economy is one of the most important and largest sectors of the German economy (generating annual revenue of EUR 245 billion or more than 10.6 percent of the country's national gross domestic product).

Germany – A Global MedTech Industry Innovator

Building on the country's rich tradition of innovation, German medical technology manufacturers achieve around one third of their total business revenue from products which are less than three years old. On average, researching companies in the medical technology sector invest around nine percent of total sales revenues in research and development. Around 170,000 people are employed in the highly specialized medical devices industry in Germany – 15 percent of whom work exclusively in the R&D field.

Germany's Innovative MedTech Research and Development Landscape

Germany is second only to the US in terms of new medical device patents and global revenue. The German government is helping improve medical device time-to-market by promoting innovations in health research and medical technology through its EUR 6.5 billion "High-Tech Strategy" R&D investment program. EUR 100 million has been set aside to support intelligent implants, innovative rehabilitation methods, imaging, and regenerative medicines research as part of the country's "Medical Devices Action Plan." Comprehensive reforms of the health care system are also promoting increased competition and improving quality of provision.

About Germany Trade & Invest

Germany Trade & Invest is the inward investment promotion agency of the Federal Republic of Germany. We assist and advise potential investors interested in Germany. Foreign enterprises planning to establish their business operations in Germany can obtain information on the business environment, such as the corporate investment framework, tax regulations, and subsidies.

Our range of services includes strategic planning, market research and competitive analysis. Our experts provide comprehensive project management and support services from site selection to the final realization of the investment. All inquiries remain confidential and our services are free of charge. We support investors from our headquarters in Berlin and from our offices in the US, China, and Japan.

More information about medical device R&D support programs and grants can be found at www.gtai.com

About BVMed

The German health care system is changing rapidly. Reimbursement of advanced medical technologies in Germany has become a crucial issue for international companies. BVMed represents round 220 industry and trade companies.

Twenty of the largest medical device manufacturers in the consumer goods sector worldwide are, among others, organized in the association. Its scope comprises the entire sector of medical dressings, technical aids (such as ostomy and incontinence products or bandages), plastic disposable items (such as syringes, catheters and cannulae) as well as the implants sector of intraocular lenses, hip, knee, shoulder and spinal implants, heart valves, defibrillators, and even artificial hearts. Homecare services and biotechnology procedures, such as tissue engineering, are further fields of activity. As a trade association, BVMed promotes and represents the combined interests of the medical technology industry and trade companies. In various sectoral interest groups, focus groups, and working groups, the association offers its members a platform for a constructive dialogue and exchange of views.

BVMed represents the concerns of its member companies to policy makers and the public in general. This is achieved not only through information and public relations work, but also by participation in the development of laws, guidelines, and standards.

Core Messages

Medical technologies are indispensable for health and quality of life. Medical technologies are an investment in the health and productivity of people. Accordingly, innovative medical technologies must be made available without delay to all patients who require them.

Notes

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