Overview of the German health-care industries:
evolution, trends and main players

Carried out on behalf and submitted to

The Ministry of Industry, Trade & Labor of Israel
Foreign Trade Administration

February 2007

Brin, Brin & Brin GbR
Reichsstr.37 • 14052 Berlin • Tel.: (030) 308 11 217 • Fax: (030) 308 11 218 •
Steuernummer: 13/241/62497• Kontonummer: 0006739520 • BLZ: 100 90 603 •
Deutsche Apotheker- und Ärztebank • Kontoinhaber: Aviva Brin, Eyal Brin & Dr. Dahlit Brin
Content

1. The German health care market - today and tomorrow ........................................ 3
   1.1. Bismarck plants the seed of the German health care system ....................... 3
   1.2. The pillars of social security ........................................................................ 4
   1.3. Costs of the health care system .................................................................... 5

2. Players within the German health care system .................................................... 9

3. Organisational structure and the financing of the German health care system 12
   3.1. Statutory Health Insurance vs. Private Health Insurance ............................. 12
   3.2. Private Health care insurances .................................................................... 12
   3.3. Statutory Health Insurance .......................................................................... 14
   3.4. The clearing system within the SHI ............................................................... 17
   3.5. Ambulatory vs. in-patient sector ................................................................. 23
   3.6. Provision of medication, and medical accessories and aids .......................... 24

4. Licensing .............................................................................................................. 25
   4.1. European Medicines Agency ....................................................................... 25
   4.1.1. Operations .................................................................................................. 25
   4.2. ISO .................................................................................................................. 26
   4.3. CE mark ......................................................................................................... 27

5. German pharmaceutical market ......................................................................... 29
   5.1. The OTC market ............................................................................................ 32
   5.2. R&D and Patent situation ............................................................................. 34
   5.3. The GKV Pharmaceutical market .................................................................. 35
   5.4. Number of drugs on the German market ..................................................... 37
   5.5. Pharmaceutical Companies ......................................................................... 37

6. The German Medical Devices Market ................................................................ 39
   6.1. Market Development ..................................................................................... 39
   6.1.1. Development in Sub-sectors ....................................................................... 39
   6.1.2. Expenditure patterns on Medical Devices .................................................. 40
   6.2. G-DRGs in the Hospital Sector .................................................................... 41
   6.3. Technical Aids ............................................................................................... 43
   6.3.1. Impact of the Healthcare Reform on the Technical Aids Sector ............... 43
   6.3.2. Federal Reference Prices .......................................................................... 43
   6.4. Homecare ...................................................................................................... 43
   6.5. Trends in Medical Technology ..................................................................... 44
   6.6. Medical Technology and Aids Companies ................................................... 46

7. Problems Germany is facing today: Socio-demographic factors ...................... 47
   7.1. Demography .................................................................................................. 47
   7.2. Health and Diseases ..................................................................................... 50
   7.3. Reasons for increasing health costs ............................................................. 52

8. Upcoming changes .............................................................................................. 53
   8.1. Integrated medical care ................................................................................ 53

February 2007
8.2. Medizinische Versorgungszentren (MVZs) ("the medical care centres")

9. The German Biotech sector ................................................................. 55
   9.1. Age Structure .................................................................................. 55
   9.2. Bio regions ...................................................................................... 56
   9.3. Areas of Biotechnology .................................................................... 58
   9.4. Sources of Equity ............................................................................. 60
   9.5. Patent situation ................................................................................ 61
   9.6. Selection of German Biotech companies according to category ....... 62

10. The German VC Market ......................................................................... 63
    10.1. Investment placements according to industry sectors ..................... 67
    10.2. Regions ......................................................................................... 69
    10.3. Exits .............................................................................................. 71
    VC Company's ..................................................................................... 73

11. Appendix: Industry and trade associations ........................................... 74
1. The German health care market - today and tomorrow

1.1. Bismarck plants the seed of the German health care system

Germany’s system of social care is deeply rooted in her history. Before 1883, mainly families and the church would provide care services, such as medical attention, clothing and food for the needy. Due to the urbanisation in the course of the industrial revolution in the 19th century the population increase drastically. Consequently, this system could no longer cater for all the needs. The need to solve this “social question”1 lay down the foundation for the modern social insurances by focusing on the concept of social welfare.

In an attempt to reduce social suffering, stabilise society and strengthen the position of the socially weak, Chancellor Bismarck2 introduced the legal requirement of compulsory school attendance at the first public schools. Additionally, he introduced the first public medical facilities, making health insurance mandatory for certain employees. Every worker and their close family were insured in this insurance and, hence, entitled to the services it held for them. This “Gesetzliche Krankenversicherung (GKV)” (statutory health insurance (SHI)) was set up in 1883. The public sector accident insurance (1889) and, what is today known as, the public sector pension insurance were also established. However, this system of care did not include care for the elderly, disabled and other patients in need of care, which was introduced as late as 1995 in form of the “Pflegeversicherungsgesetz (PVG)” (law regarding care for the elderly). This statutory social insurance system is named “Bismarck system”, after the chancellor who introduced it.

The number of citizens covered by health insurance doubled from 1880 to 1883, and grew from 10% of the population in 1983 to 88% in 19873. This increase in

---

1 Which formed the basis for the development of the labour movement and Trade Unions
2 Otto Eduard Leopold, Prince von Bismarck, Duke of Lauenburg (April 1, 1815 – July 30, 1898) was one of the most prominent European statesmen of the nineteenth century. As minister-President of Prussia from 1862 to 1890, he engineered the unification of the numerous states of Germany. From 1867 on, he was Chancellor of the North German Confederation. When the German Empire was declared in 1871, Bismarck served as its first Chancellor.
3 Source: Alber 1992 (17); Federal Statistical Office (4), Federal Ministry of Health 2004
membership was achieved by raising the income ceiling for the mandatory membership and by adding new occupational groups to the sickness funds system.

In 1947, as a consequence of World War II, the Social Market Economy (SME) was founded. A system of an efficiently operating market economy with a social net to make up for free market failures emerged. This critical new orientation occurred shortly after the inauguration of the FRG⁴, where for the first time an individual was legally entitled to social services provided by the government. A state funded system catering for the needs of the elderly was founded within the context of SME. The first nursing homes, residential homes and homecare services were set up, substituting the traditional way of providing care for the elderly and disabled.

While Bismarck’s system still forms the basis of Germany’s social system, over the years slight changes have been made to it.

1.2. The pillars of social security

The German welfare state rests on 3 pillars, namely, “Social insurance” or “Social security”, “Provision and Social adjustment”, and “Relief” (see Diagram 1). Social insurance covers all health related costs, including sickness (health) insurance, accident insurance, pension payments, unemployment payments and care insurance (which regards care for the elderly and disabled).

⁴ Federal Republic of Germany
The other two pillars, provision and social adjustment and relief, do not concern the German health care industry.

1.3. Costs of the health care system

The German health care expenditure levels rose by a total of 40.6% between 1993 and 2003, or an average annual growth rate of 4.06% (see Graph 1), reaching €239 billion. In 2003, the largest category was health care goods (27%), followed by services provided by doctors (26%), and care and therapeutic services (23%).
The group with the highest increase was care and therapeutic services with an annual average growth rate of 6.6%, followed by goods (4.9%) and administration (4.4%).

In terms of health care expenditure as a percentage of GDP, Germany was the third largest country with 11.1% according to Federal statistical office (see graph 2). She was preceded by the US and Switzerland.
In 2005, the statutory health insurance companies spend a total of €140,549 million. These expenditures can be viewed as being made up of three major groups – medical treatment (excl. dental), medication and aid facilities and all other (see graph 3).
Medical treatment (excl. dental), either through hospitals or doctors, consisted of a combined 50.3% of statutory expenditures, of which ambulatory treatment amounted to less then a third. Medication and aid facilities added up to 20%, of which medication made up nearly 85%. Dental treatment and dentures made up an additional 5.4%.
2. Players within the German health care system

The German health care system is composed of a wide variety of players. In 2004\(^5\), the total health personal amounted to 4,235,000 of which 306,000 were physicians, 65,000 dentists, 56,000 pharmacists and 1,816,000 covered other health professions. Graph 4 depicts a further, more detailed account of the distribution of health care personal.

![Graph 4: Health personnel 2004 by providers and type of occupation (in 1,000)](image)

Data Source: The Information System of the Federal Health Monitoring

In 2005, there were 2,139 hospitals in Germany providing a total of 523,824 beds. 16,874 cases were recorded, with an average length of stay of 8.6 days. The average bed occupancy rate was 75.6% (of all available beds)\(^6\). Overall a gradual downward

---

\(^5\) Latest available figures.

\(^6\) Federal Statistical Office
trend in the availability of hospital beds has been observed. This trend is to be continued and actively supported by the government.

There are 16 Länder organisations and several other associations for different types of hospitals. There are three main groups of hospitals:
1. Public hospitals (“Öffentliche Krankenhäuser”), which are run by the local authorities, the towns and the “Länder”.
2. Voluntary non-profit hospitals (“Frei gemeinnützige Krankenhäuser”) operated by the churches or non-profit organisations, e.g. German Red Cross.
3. Private Hospitals (“Privatkrankenhäuser”) are managed as free commercial enterprises.

Other important groups of players are those providing medical products and aids\(^7\), pharmaceuticals, and rehabilitation\(^8\). Furthermore, a variety of institutions provide a wide range of both ambulatory, in-patient and home care services. Furthermore, there are also different government institutions and other authorities that are main players in the health care system.

All players need to interact in order to provide the numerous health services (see diagram 2).

---

\(^7\) Medical products refer to all goods or services that contribute to the healing process, improvement or prevention of a disease or other medical condition, e.g. physical or speech therapies, orthopaedic aids (e.g. wheelchairs or artificial limbs) or visual aids (e.g. glasses). A large part of medical aids and products can be acquired in orthopaedic shops and pharmacies.

\(^8\) Rehabilitation is divided into different categories. The type of rehabilitation relevant in the current context is medical rehabilitation. Different bodies are responsible for the payment of various rehabilitation measures, e.g. insurance companies and local authorities.
Diagram 2: Players within the health care system

Physicians
- Urologists
- Radiologists
- Surgeons
- Orthopedists
- Neurologists
- Ophthalmologists
- Throat-nose-and-ear
- Internists
- Dermatologists
- Gynaecologist
- Paediatricians
- General practitioner
- Anaesthetist
- Doctors also engaged in psychotherapy

Dentists
Psychotherapists & psychiatrists

Other medical and related professions
- Physiotherapists
- Speechtherapists
- Opticians

Medical institutions
- Hospitals
- Rehabilitation
- Care
- Medical emergency services

Orthopaedics shops

Pharmacies
- Hospital-internal
- Non-hospital affiliated

Pharmaceutical companies

Government offices and ministries
- Health ministry
- Robert Koch Institute
- Etc.

Institutions
- Chambers of Physicians
- Union of sickness funds
- Etc.

Source: MIP
3. Organisational structure and the financing of the German health care system

3.1. Statutory Health Insurance vs. Private Health Insurance

A defining characteristic of the German political system is the sharing of decision-making processes and powers among the so called “Bundesländer”⁹, the central government and special civil society organisations. This system is of specific significance for the German health care system. Statutory health insurance is financed by a statutory contribution system that ensures free healthcare for all via sickness funds (Krankenkassen). These insurance payments are based on a percentage of income, which are partially paid by employee and partially by the employer. In addition to the Statutory Health Insurance (there are private health care insurances (PHIs) (“Private Krankenversicherungen”, PKV). The SHI plays a central role in the German healthcare system. The majority of the population (approximately 90%) is covered by it. Membership in the SHI is compulsory for all who earn up to €47,700 p.a. pre tax¹⁰. Private healthcare schemes are utilised by those who earn above the aforementioned income level and use it as an alternative to the SHI. Others use private health care insurance in order to upgrade the health care services provided by the state.

3.2. Private Health care insurances

Private Health care insurances are for profit organisations, such as publicly traded corporate companies or “Anstalt des öffentlichen Rechts” (institution according to public law). PHIs are mandatory members of the national union of private health care insurances (“Verband der privaten Krankenversicherung e.V.”). Members of this association are supervised by the state through the “Bundesaufsichtsamt für das Versicherungswesen” (Federal supervisory office for the insurance system) and the relevant Länder office.

Private health insurances calculate the premiums according to the type of coverage the insuree requests and according to the level of risk he carries for the insurance company. The risk

⁹Bundesländer or Länder are individual states within Germany, such as Berlin-Brandenburg, Bavaria or Lower Saxony. Germany has a total of 16 Länder.
¹⁰This income limit changes (usually increases) every year. The amount mentioned here applies to 2007.
element will be calculated independent of the insuree’s income. There are cases where family members of an insuree receive cover for a reduced premium. However, unlike in the SHI there is no possibility to ensure a family member for free.

Services delivered to patients with private medical insurance are paid according to a special benefit code each for doctors and dentists (“Gebührenordnung für Ärzte”, GOÄ and “Gebührenordnung für Zahnärzte”, GOZ). The service provider sends invoices, which are based on these benefit codes, to the patients. The patients pay these invoices and forward the receipts onto the private sickness funds, who, in turn reimburse the patients. This process also applies to pharmaceuticals and medical aids.

In case of hospital stays, privately insured patients may choose to utilise the services that are provided to SHI patients, in which case the hospital will receive the same payments as for an SHI patient. In case a privately insured patient wishes additional services that he is entitled to via his or her insurance, an invoice based on the GOÄ is sent to the patient for these additional services.

The following 36 private insurances make up over 99% of market share (as of February 2007):

1. Allianz Krankenversicherung
2. Alte Oldenburger Krankenversicherung
3. ARAG Krankenversicherung
4. AXA Krankenversicherung
5. Barmenia Krankenversicherung
6. Bayerische Beamtenkassenkasse
7. BBV Krankenversicherung
8. Central Krankenversicherung
9. Concordia Krankenversicherung
10. Continentale Krankenversicherung
11. DBV-Winterthur Krankenversicherung
12. Debeka Krankenversicherung
13. Deutscher Ring Krankenversicherung
14. DEVK Krankenversicherung
15. DKV Deutsche Krankenversicherung
16. Globale Krankenversicherung (merged with DKV)
17. Gothaer Krankenversicherung
18. Hallesche Krankenversicherung
19. Hanse-Merkur Krankenversicherung
20. HUK-Coburg Krankenversicherung
21. Inter Krankenversicherung
22. Karstadt-Quelle Krankenversicherung
23. LKH Landeskrankenhilfe
24. LVM Krankenversicherung
25. Mannheimer Krankenversicherung
26. Mecklenburgische Krankenversicherung
27. Münchener Verein Krankenversicherung
28. Nürnberger Krankenversicherung
29. R+V Krankenversicherung
30. SDK Süddeutsche Krankenversicherung
31. Signal Krankenversicherung
32. UKV Union Krankenversicherung
33. Universa Krankenversicherung
34. Victoria Krankenversicherung
35. Württembergische Krankenversicherung
36. Zürich Krankenversicherung (merged with DKV)

3.3. Statutory Health Insurance

The most prominent part of the German health care system is the Statutory Health Insurance. Traditionally, governments delegate competencies to membership-based and self-regulated organisations of payers and providers, such as the “Association of Statutory Health Insurance Physicians” (Kassenärztliche Vereinigung, KV). These organisations focus on the provision and financing of health care services and products that are covered by the SHI.

The SHI, the sickness funds and their unions, as well as the unions of doctors working with the SHI are quasi-public corporations. These parties make up the self-regulated structures that
operate the financing and delivery of payments (in kind and monetary) covered by the SHI. This whole framework is rooted in an extensive legal framework.

Special committees made up of payers (union of sickness funds) and service providers (union of doctors, dentists or individual hospitals) decide about the types of goods and services that are to be provided by the SHI, define standards (at the federal level) and prices, as well as negotiate contracts between various parties. Another important duty carried out by these committees is the controlling and supervision of the health care providers, in order to avoid fraud and ensure optimal health care provision to the members of the SHI\textsuperscript{11}.

In order for a physician to work with the SHI, he or she needs to have a mandatory membership in the “Association of Statutory Health Insurance Physicians” (Kassenärztliche Vereinigung, KV). This union is organised on a regional, usually Länder, level, headed by the federal umbrella organisation “Kassenärztliche Bundesvereinigung, (KBV)“ (Federal association of statutory health insurance physicians). Representatives of this union are elected democratically. SHI-affiliated dentists are organised in the same manner. In order to provide health care services to patients with private health care insurance, no mandatory membership in any organisation is required. Physicians do not have to choose between treating solely private or SHI patients. They can do both, however, the clearing system and payments for either type of insurance is different.

In addition to these parties, further bodies have increasingly gained decision-making rights in the health care system over the recent years. Examples of these are private health care companies that have negotiating power regarding payments to hospitals or consultants from various health professions. The social courts (“Sozialgericht”) also play an important role in the decision-making processes. It is here where parliamentary laws and state regulations may be challenged. Examples of such are patients objecting decisions made by the SHI regarding non-payments for goods and services they feel necessary.\textsuperscript{12} Doctors who are affiliated to the SHI may oppose to the exclusion or non-admittance of specific medical goods or services in the ambulatory medical services package.

\textsuperscript{11} For further information on the decision making process regarding the SHI see page 19, Diagram 4
\textsuperscript{12} This will be done in conjunction with a medical committee
The German constitution ("Grundgesetz") demands all living conditions to be equal across all Länder. However, health care is not included in the definition of living conditions and, thus, is decided upon on the Länder level and not on the federal level. Health matters are decided upon on different levels, according to the type of issue in focus.

The federal government decides on specific topics, such as social benefits, safety measures in the interest of safekeeping public health, radiation protection, certification of doctors and other health professionals, pharmaceutical and drugs, and level of economising within hospitals. All other issues are managed on a Länder level. Federal law always takes precedence over Länder law.

The main bodies at the federal level are The Federal Assembly (Bundestag), Federal council ("Bundesrat") and the Federal Ministry of Health (Bundesministerium für Gesundheit). Connected to the Health ministry are a series of other commissions, such as the Narcotic Drug commissioner of the Federal government ("Bundesdrogenamt"), the commissioner of the federal government for the concerns of patients. A series of committees and the Advisory council for evaluating the development in health care act as consultants to the health ministry. Additionally, a number of subordinate authorities assist the health ministry in executing licensing and supervisory functions, scientific consultancy work and in providing information services to the general public or professional circles. These sub-ordinate authorities include:

- "BfArM" – „Das Bundesinstitut für Arzneimittel und Medizinprodukte“ (Federal Institute for Drugs and Medical Devices)
- Federal Institute for Sera and Vaccines (Paul-Ehrlich-Institute)
- "Robert Koch-Institute" - The Federal Institute for Communicable and Non-Communicable Diseases. Its responsibility is to detect, monitor, prevention and control diseases. It is responsible for issuing and publishing health reports and epidemiological bulletins.
- “BZgA” – “Bundeszentrale für gesundheitliche Aufklärung (The Federal Centre for Health Education).
- “DIMDI” – “Deutsches Institut für Medizinische Dokumentation und Information”. The German Institute for Medical Documentation and Information has the task of providing information to the public and professionals in all fields of the life sciences sector.
At the Länder level, “health” is an area that is included alongside other topics, such as social and family issues or labour-related offices. Within a Länder office responsible for health matters, there usually are a number of subordinate offices or divisions that focus on specific health issues, such as family planning, public health services and environmental hygiene, or pharmaceuticals and the supervision of pharmacists and their professional institutions.

Increasing decision-making right in the SHI structures has been granted to the German Hospital Organisation. It represents the interests of hospitals based on private law. While hospitals are not a public or quasi-public institution they increasingly receive legal responsibilities, too.

Payments for the services provided for by the Statutory Health Insurance are made by sickness funds, that are organised either on a regional or federal level. The market has seen a heavy consolidation of sickness funds, leaving it with 136 statutory sickness funds at present. These are divided into local sickness funds (“Ortskrankenkasse”), corporate affiliated sickness funds (“Betriebskrankenkassen”), gilds sickness funds (“Innungskrankenkassen”), compensation sickness funds (“Ersatzkassen”), and further smaller funds. The AOK (Allgemeine Ortskrankenkasse) is the largest single player in the market. The main differences between each one lies in their additional benefits (“Zusatzleistungen”). With respect to the types of members, levels of premiums, benefits and financing the differences are only marginal. All these sickness funds have a non-for profit status and are self-governed.

3.4. The clearing system within the SHI

The association of SHI physicians negotiates each year with the SHIs regarding the total sum of payments for all member physicians. This total budget is distributed among all member groups and then individual physicians. The clearing system is a very extensive and complicated one.

---

13 Member groups are the groups according to which the individual physicians are categorised. For example, one member group refers to general practitioners and another to cardiologists.
To each service, such as diagnostic method or treatment, a special amount of points is allocated. These points are then translated into money, according to the current monetary value, which constantly changes. Hence, the total sum of payments that a doctor to receive results from the total sum of points he has accumulated via the services he provided his patients. However, there are certain mean or norm values for each member group. In case a physician surpasses these norms, the total sum of points will be reduced according to a pre-defined system. A repeated, non-justified and non-permitted surpassing of these norms will lead to drastic cuts in the payments and financial penalties. The permitted maximum amount of points can be increased and/or an extra budget can be obtained through extra qualifications and permissions by the association.

Members of the SHI receive a member chip card with which he can receive the medical services of an SHI affiliated physician. As stated above, the majority of the German population is insured via the SHI, either as a full member, family member (i.e. insured via a family member, which usually is the case for children who are insured via their parents) or voluntary member (those who earn above the SHI binding income level and opt to join the SHI). Premium payments in the SHI are based on the solidarity principle, meaning that every member pays according to his ability, in form of a set percentage of income, and receives the treatment needed. Unlike in the private health insurances, risks in form of health hazards or age are not taken into account in the premium calculations.

The benefits from the state sickness funds usually come in form of services that the patient may utilise or in kind (e.g. medical aids, utilities and medication). In some cases direct financial payments and re-imbursements are made.

Each SHI affiliated hospital needs to re-negotiate annually with each individual paying party. Per patient a specific sum is agreed upon. This sum includes payments for medical treatment, care, medication, food and accommodation. Additionally there are special rates that apply to specific wards, case-bound lump sum payments and extra payments in exceptional cases.

Since 2004, the clearing system for hospitals is being transformed to a diagnosis related groups (DRG)-case lump sum payment, as is already the standard in many European countries. The amount of this lump sum is influenced specifically by the type of illness (i.e. diagnosis), operation and degree of illness (i.e. severity). The DRG case-sum covers the total
costs of the required treatments including operations, accommodation, food and other services that may be necessary. Costs of in-patient care makes up for the majority, approximately a third, of all SHI expenditures.

In addition to the sickness funds (statutory or private), local governments finance non-private hospitals. For this reason this form of financing is called “Dual financing system”. Each Land draws up hospital plans in order to ensure that there is sufficient medical care available for all patients in the Land. The anticipated need is translated in “planned beds”, which are distributed over a number of hospital in that Land. Each hospital that is included in the hospital plan as an affiliate provides a certain number of planned beds, and receives an accompanying lump sum for each such bed. Additionally these hospitals may apply for special subsidies. Running costs, such as for treatments, are covered by the patients via their sickness insurances (either SHI or PSF) and self-participation (by the patients).

Another important type of institution is the professional chamber. In order to practice medicine all physicians, regardless of whether they work with the SHI, need to be a member in the chamber of physicians, “Ärztekammer”. The Ärztekammer is organised according to the Länder level, headed by the Federal chamber of physicians – “Bundesärztekammer” BKV. It plays an active role in the opinion-forming of health policy in society and in legislative procedures.

The German Medical Assembly can be seen as the "parliament of the medical profession", where delegates from the chamber of physicians gather annually. At the German Medical Assembly, professional regulations (such as the model professional code and the model postgraduate training regulations) that apply nationally are elaborated and adopted. Further, policies regarding the medical profession in topical health-related and socio-political debates in society are decided upon and communicated to the general public.

There are numerous further organisations that are related to the health care sector. However, there are too many to mention here and the most important ones have been or will be discussws in this text. Diagram 3 shows the flow of finances, services and benefits among the various players within the Statutory Health insurance.
The competencies and interrelationships of all the main actors in the decision-making processes involved in the Statutory Health Insurance are shown in diagram 4 and table 1 below.
Diagram 4: The organizational relationships of the key actors in the health care system

Source: Health care systems in transition, 2004, Busse Riesberg
### Table 1: Decision-making competencies in the German health care system

<table>
<thead>
<tr>
<th>Area</th>
<th>Coverage decisions</th>
<th>Licensing/ Accreditation</th>
<th>Financing decisions</th>
<th>Quality assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ambulatory care (primary and secondary care)</strong></td>
<td>basic definition by federal law; details mainly delegated to actors on federal level</td>
<td>basic definition by federal law; details delegated to actors on federal (rules) and Länder (actual implementation) levels</td>
<td>mainly delegation to actors on Länder level, limited since 1999 as increases in regional budgets are limited by federal law</td>
<td>mandated by federal law (internal QM); details delegated to actors on federal (rules) and Länder (actual implementation) levels</td>
</tr>
<tr>
<td><strong>In-patient care</strong></td>
<td>until 1999 implicitly included in financing decisions; since 2000 mainly delegated to actors on federal level</td>
<td>de facto by Länder governments; Legally sickness funds may de-contract hospitals, but the final decision is taken by the Land government.</td>
<td>capital financing: mainly “bottom-up devolution” by Länder; running costs: delegation to actors on local level, preparation of the DRG system mainly federal level with substitutive execution by federal government</td>
<td>mandated by federal law (internal and external QM); actual implementation delegated to actors on Länder level</td>
</tr>
<tr>
<td><strong>Trans-sectoral care</strong></td>
<td>basic definition by federal law; details delegated to actors on federal (rules) and Länder (actual implementation) levels</td>
<td>basic definition by federal law; details delegated to actors on federal (rules) and Länder (actual implementation) levels</td>
<td>basic definition by federal law; details delegated to actors on federal (rules) and Länder (actual implementation) levels and selective contract partners</td>
<td>basic definition by federal law; details delegated to actors on federal (rules) and Länder (actual implementation) levels and selective contract partners</td>
</tr>
<tr>
<td><strong>Dental care</strong></td>
<td>basic definition by federal law; details mainly delegated to actors on federal level</td>
<td>basic definition by federal law; details delegated to actors on federal (rules) and Länder (actual implementation) levels</td>
<td>mainly delegation to actors on Länder level; limited since 1999 as increases in regional budgets are limited by federal law</td>
<td>basic definition by federal law; details delegated to actors on federal (rules) and Länder (actual implementation) levels</td>
</tr>
<tr>
<td><strong>Pharmaceuticals</strong></td>
<td>mixture of governmental regulation (negative list; in future positive list) and delegation to actors on federal level</td>
<td>Basic definition by federal and EU law; licensing by governmental agency at federal level or EU agency</td>
<td>Legal definition of wholesaler and pharmacy surcharges for prescription drugs; ex-factory prices mainly manufacturer’s decision; delegation of reference price setting and aut-ident to actors at federal</td>
<td>Basic definition by federal law; pharmacovigilance by the governmental and European licensing agency at federal level; details and implementation of prescription quality improvement delegated to actors at federal and</td>
</tr>
</tbody>
</table>
This statutory health insurance is based on the principles of solidarity and pay-as-you-go, and built upon existing voluntary or mandatory local social insurance programmes. Monetary and in-kind benefits are financed by proportional contributions from mandatory and voluntary members as well as their employers. The sickness fund operates via self-governmental structures, which also decide about benefit coverage beyond the legally defined scope.

### 3.5. Ambulatory vs. in-patient sector

The provision of healthcare in Germany can be broadly separated into ambulatory and in-patient sectors. Ambulatory health services are mainly provided by self-employed doctors (and their assistants), dentists, psychotherapists, medical practitioners, physiotherapists, massagers and pharmacists. The health care system further differentiates between family (or general) practitioners and specialised physicians (such as cardiologists, gynaecologists or specialised general practitioners).

Service providers of ambulatory health care are either located in their own practices, in practice unions, special “physician houses” (“Ärztehäuser”) or in hospitals. There are 24-hour emergency ambulatory medical and dental services available to all patients.
In-patient care is provided by hospitals, institutions for preventative medicine, rehabilitation institutions, full and partial care institutions, emergency services and transportation services.

In addition to the above mentioned institutions, there are some state “Health offices” ("Gesundheitsämter"). These provide a limited range of ambulatory services, such as diagnostics and consultation. However, the majority of services are provided by the self-employed physicians mentioned above.

The payment of the services provided either by an ambulatory or in-patient health care provider depends on the type of insurance the patient has. While there are some institutions that only accept privately insured patients, most medical service provider will accept patients with either type of insurance.

3.6. Provision of medication, and medical accessories and aids

Pharmacies are responsible for the provision of pharmaceuticals and the delivery to the end-user. Pharmaceuticals need to acquire a license from the Federal Institute for pharmaceuticals (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), while vaccinations need to be licensed by the Paul-Ehrlich-Institut.

There are 4 risk levels according to which pharmaceuticals are categorised. The most important or prevalent category are medications where a prescription is required. The two main types of pharmacies are those affiliated to hospitals and the independent ones. Pharmacies affiliated to hospitals are also required to provide the hospital with all their medication requests and to monitor the movement of medication within the hospital.

Pharmaceuticals companies deliver their products to so called “Grossapotheaken” (Grand Pharmacies) which act as wholesalers. In turn, they distribute the products to the pharmacies. The non-hospital affiliated pharmacies, i.e. the individual pharmacies, act as suppliers to patients and doctors practices.

Prices for medications are legally set and cannot be altered. In Germany each pharmacist is allowed to own one pharmacy only. Each pharmacy is required to deliver emergency services on a regular, rotary basis.
4. Licensing

4.1. European Medicines Agency

The European Medicines Agency (EMEA) is a London based agency for the evaluation of medicinal products and is often described as the European counterpart to the U.S. Food and Drug Administration (FDA). The EMEA was set up in 1995, with funding from the European Union and the pharmaceutical industry, as well as through indirect subsidies from member states. The aim was to harmonize (but not replace) the work of existing national medicine regulatory bodies. It replaced the Committee for Proprietary Medicinal Products set up in 1977 and the Committee for Veterinary Medicinal Products, though both of these were reborn as the core scientific advisory committees. Until 2004, the European Medicines Agency was known as the European Agency for the Evaluation of Medicinal Products.

The aim of EMEA is to substantially reduce the annual cost of $350 million incurred by pharmaceutical companies, who have to seek approval from each member state to market their products. Another important aim of EMEA is the elimination of "protectionism" that some member states have demonstrated, which involved the refusal to approve new drugs that may compete with domestically produced ones.

4.1.1. Operations

EMEA operates as a decentralized scientific agency (as opposed to a regulatory authority) of the EU. It is responsible for the protection and promotion of human and animal health, specifically through the coordination of evaluation and monitoring of centrally authorized products and national referrals, developing technical guidance and providing scientific advice to sponsors. Its scope of operations covers medicinal products for human and veterinary use including biologics/TEPs and herbal medicinal products. EMEA is organized into four units: human medicine, veterinary medicines and inspections, communications and networking, and administration.

---

14 It is an open secret that the highest local EU standards are set by the German governing bodies, while the lowest can be found in the UK.
An application for a marketing authorization to the EMEA is submitted for products eligible for or requiring central approval. A single evaluation is carried out through the Committee for Medicinal Products for Human Use (CHMP) or the Committee for Medicinal Products for Veterinary Use (CVMP). The EMEA’s Committee on Orphan Medicinal Products (COMP) administers the granting of orphan drug status. The fourth committee at EMEA is the Committee on Herbal Medicinal Products (HMPC). It assists the harmonization of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework.

If the relevant Committee concludes that quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. This approval is sent to the European Commission to be transformed into a marketing authorization valid for the whole of the European Union. The CHMP and CVMP are obliged by the Regulation to reach decisions within 210 days, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. This compares well with the average of 500 days taken by the FDA.

Although the majority of existing medicines throughout the European Union's member states remain authorised nationally, the bulk of genuinely novel medicines are authorised through the EMEA.

4.2. ISO

The *International Organization for Standardization (ISO)* is an international standard-setting body composed of representatives from national standards bodies. Founded on February 23rd 1947, the organization produces world-wide industrial and commercial standards, the so-called ISO standards.

While the ISO defines itself as a non-governmental organization (NGO), its ability to set standards which often become law through treaties or national standards makes it more powerful than most NGOs, and in practice it acts as a consortium with strong links to governments. At the end of 2006, out of the 198 countries in the world 158 were members.
ISO cooperates closely with the International Electrotechnical Commission (IEC), which is responsible for standardization of electrical equipment.

The ISO standards are not in any way binding on either governments or industry merely by virtue of being international standards. This is to allow for situations where certain types of standards may conflict with social, cultural or legislative expectations and requirements. This also reflects the fact that national and international experts responsible for creating these standards do not always agree and not all proposals become standards by unanimous vote. The individual nations and their standards bodies remain the final arbiters.

4.3. CE mark

The CE mark (officially CE marking) is a mandatory safety mark on many products placed on the single market in the European Economic Area (EEA), and is now used in all EU official documents. By affixing the CE marking, the manufacturer, or its representative, or the importer assures that the item meets all the essential requirements of all applicable EU directives.

The CE mark is a mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives. The CE Marking is a mandatory mark for ca 70% of all products sold on the EFTA plus European Union (EU) market (total 28 countries) and it is often referred as the "Trade Passport to Europe" for non-EU products. In general, the CE Marking is required for 22 groups of products, including medical devices, active implantable medical devices and in vitro diagnostic medical devices.

To permit the use of a CE mark on a product, proof that the item meets the relevant requirements must be documented. Sometimes this is achieved using an external test house which evaluates the product and its documentation. Often it is achieved by a company-internal self-certification process. In any case the responsible organization (manufacturer, representative, importer) has to issue a EC-Declaration of Conformity (EC-DoC) indicating his identity (location, etc.), the list of European Directives he declares compliance with, a list of standards the product complies with, and a legally binding signature on behalf of the
organization. The EC-DoC underlines the sole responsibility of the manufacturer. The CE marking could be licensed from 3rd party test houses / certification bodies; in that case the CE symbol also includes a number that identifies the 3rd party body.

Directives providing the requirements for the CE mark are created by the European Union (EU), but the markings are required throughout the European Economic Area (EEA), which also includes the European Free Trade Association (EFTA) members Norway, Iceland, and Liechtenstein, and in Turkey, which is not a part of the EU or the EFTA. (Switzerland is the only nation that is part of the EFTA (or the EU), but not the EEA. According to information provided by the Swiss Government for Swiss Exporters the CE Mark is not compulsory in Switzerland except for products for export to the European Union.)

EU legislation, e.g. EU directive concerning Liability for Defective Products, make EU importers liable for the products they import, including the machinery they provide to their employees for work. Many non-EU exporters are finding that no matter how interested a prospective EU importer may be in the product, the importer will not risk importing non-conforming products (i.e. the products without CE Marking) which, in case of accident, may generate legal action against them. The liability claims in a law suit can be as high as €70 millions.

CE Marking may be achieved through several modules. One of the most practical ways, which is preferred by many EU importers who are neither specialized in the complicated CE Marking process nor willing to take risk, is that the manufacturer designates an Authorized Representative in the EU member states who will handle the CE Mark approval, CE testing issues and ensure to meet the CE mark requirements, meanwhile the importers and/or distributors focus on the marketing and sales of the products.

The manufacturer may need only one authorized representative in EU whereas may have many importers and/or distributors. The Authorized Representative may in some cases register the product(s) in the EU member states and thus obtain a Certificate of Registration.
5. German pharmaceutical market

The gross income in the German pharmaceutical industry, evaluated according to manufacturer selling prices, rose by 5.89% in 2005, compared to the previous year, reaching €21.9 billion (see graph 5).

Graph 5: Total sales revenues of the pharmaceutical market 2002-2005 (€ 'million)

This raise is mainly due to the development of the anaesthetics, which increased by 25.84%. The prescription-requiring pharmaceuticals experienced a rise of 6.34% (see table 2).

Table 2: Sales revenues according to categories (€ 'mil) - 2002-2005

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>19,249.6</td>
<td>20,634.5</td>
<td>20,682.9</td>
<td>21,900.4</td>
</tr>
<tr>
<td>Anesthetics</td>
<td>317.8</td>
<td>395.4</td>
<td>486.4</td>
<td>612.1</td>
</tr>
<tr>
<td>Prescription required</td>
<td>14,488.4</td>
<td>15,834.4</td>
<td>16,017.7</td>
<td>17,033.0</td>
</tr>
<tr>
<td>Obtainable in pharmacies only</td>
<td>3,382.4</td>
<td>3,293.8</td>
<td>2,862.0</td>
<td>2,891.0</td>
</tr>
<tr>
<td>Non drug</td>
<td>749.9</td>
<td>884.5</td>
<td>1,104.8</td>
<td>1,159.8</td>
</tr>
<tr>
<td>Narcotics and Chemicals available outside pharmacies</td>
<td>4.6</td>
<td>5.0</td>
<td>5.0</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Source: Insight Health 2006
When analysing the pharmaceutical market from the quantitative aspect, a similar growth rate emerged (see table 3). However, a decrease of 5.38% in the non-pharmacy-required drugs category was observed.

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>1.703,5</td>
<td>1.702,6</td>
<td>1.5967</td>
<td>1.619,2</td>
</tr>
<tr>
<td><strong>Anesthetics</strong></td>
<td>5,2</td>
<td>5,9</td>
<td>6,4</td>
<td>7,3</td>
</tr>
<tr>
<td><strong>Prescription required</strong></td>
<td>732,1</td>
<td>756,5</td>
<td>686,0</td>
<td>701,6</td>
</tr>
<tr>
<td><strong>Obtainable in pharmacies only</strong></td>
<td>801,9</td>
<td>778,1</td>
<td>706,6</td>
<td>715,4</td>
</tr>
<tr>
<td><strong>Non-drug</strong></td>
<td>98,4</td>
<td>101,5</td>
<td>141,8</td>
<td>142</td>
</tr>
<tr>
<td><strong>Narcotics and chemicals</strong></td>
<td>0,8</td>
<td>0,8</td>
<td>0,7</td>
<td>0,7</td>
</tr>
<tr>
<td><strong>available outside pharmacies</strong></td>
<td>65,1</td>
<td>59,7</td>
<td>55,2</td>
<td>52,3</td>
</tr>
</tbody>
</table>

Source: Insight Health 2006

The development of the pharmaceutics segments turnover according to auxiliary classes shows the largest increases in the Diagnostics sector (8.51%), followed by Anthroposophics (7.79%) and human pharmaceuticals (6.14%) (see table 4)

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anthroposophy</strong></td>
<td>34,3</td>
<td>35</td>
<td>30,1</td>
<td>32,5</td>
</tr>
<tr>
<td><strong>Human medication</strong></td>
<td>17078,2</td>
<td>18462,7</td>
<td>18458,7</td>
<td>19592,8</td>
</tr>
<tr>
<td><strong>Diagnostics</strong></td>
<td>487,4</td>
<td>477,5</td>
<td>510,4</td>
<td>553,8</td>
</tr>
<tr>
<td><strong>Homoeopathic medication</strong></td>
<td>240,2</td>
<td>235,2</td>
<td>222,4</td>
<td>232,7</td>
</tr>
<tr>
<td><strong>Phytopharmacy</strong></td>
<td>982,2</td>
<td>947,6</td>
<td>828</td>
<td>849,8</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td>427,3</td>
<td>476,5</td>
<td>633,3</td>
<td>638,9</td>
</tr>
</tbody>
</table>

Source: Insight Health 2006

However, when looking at the total amount of units sold, Anthroposophy experienced a 9.80% increase, followed by Diagnostics (7.92%) and Homoeopathic medication (5.61%) (see table 5).
Table 5: Sales development of the medicament segments according to categories – 2002 - 2005 (in million units)

<table>
<thead>
<tr>
<th>Segment</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthroposophy</td>
<td>5</td>
<td>4,9</td>
<td>4,7</td>
<td>5,1</td>
</tr>
<tr>
<td>Human medication</td>
<td>1,347,20</td>
<td>1,362,40</td>
<td>1,244,50</td>
<td>1,264,00</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>22,1</td>
<td>22,1</td>
<td>23,3</td>
<td>25,1</td>
</tr>
<tr>
<td>Homoeopathic medication</td>
<td>49,1</td>
<td>47,8</td>
<td>45,9</td>
<td>48,5</td>
</tr>
<tr>
<td>Phytopharmacy</td>
<td>185,9</td>
<td>170,7</td>
<td>154,5</td>
<td>155,5</td>
</tr>
<tr>
<td>Others</td>
<td>94,1</td>
<td>94,6</td>
<td>123,9</td>
<td>121</td>
</tr>
<tr>
<td>Total</td>
<td>1,703,50</td>
<td>1,702,60</td>
<td>1,596,70</td>
<td>1,619,20</td>
</tr>
</tbody>
</table>

Source: Insight Health 2006

The sales revenues of prescription drugs (excluding prescribed OTC) made up 83% of total pharmaceutical sales revenues in 2005 with a gross income of approximately €28.9 billion (graph 6). The total OTC market (both self-medicated and prescribed OTC's) generated nearly €6 billion.

Graph 6: Sales revenues 2005 (€ bil)

However, in terms of packaging units sold prescription drugs (excluding prescribed OTC) only made up 48% (688 million units), followed by self-medicated OTC's (41.5%, 593 million units). Prescribed OTC, i.e. those refunded by the GKV, made up 10.5% (147 million units) (graph 7)
The differences between the market share of sales revenue and sales turnover in terms of units can be found in the price difference of these two (OTC and prescription drugs). The average selling price for prescription drugs is approx. €40, which is nearly six times as much as the average price for OTC's, which is €8.05.

5.1. The OTC market

The OTC market is made up of three sectors:

1. those drugs that are OTC but have to be sold in a pharmacy
2. those that are free for sale everywhere (e.g. supermarkets)
3. food supplements and similar products.

In 2005, the OTC market totalled over €6.7 billion, a slight increase (1.2%) compared to 2004. However, it is still lower than the 2002 and 2003 levels (see Table 6).

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy only</td>
<td>6,378.430</td>
<td>6,347.920</td>
<td>5,497.728</td>
<td>5,529.331</td>
</tr>
<tr>
<td>Free sales</td>
<td>384.254</td>
<td>379.305</td>
<td>368.999</td>
<td>350.075</td>
</tr>
<tr>
<td>GMS Pharmacy</td>
<td>544.632</td>
<td>645.999</td>
<td>752.342</td>
<td>820.650</td>
</tr>
<tr>
<td>Total</td>
<td>7,307.316</td>
<td>7,373.224</td>
<td>6,619.069</td>
<td>6,700.056</td>
</tr>
</tbody>
</table>

Source: Insight Health 2006
Although the segment of OTC's that can only be purchased in pharmacies is still dominating with 82.6% in 2005 – compared to 87.3% in 2002 – it is slowly decreasing in favor to GMS pharmacies (see graph 8). In fact, the former experienced a 13.3% loss in sales revenues between 2002 and 2005, while the later an increase by more than 50% during the same period (see table 6).

![Graph 8: OTC Market share according to sales revenue - 2002 to 2005](image)

In terms of units sold, every fifth drug sold in pharmacies does not require a special license to be sold. This trend started in 2002, and is particular evident in those products that are labelled as food supplements. This higher demand is also reflected in the increase of prices in this category, from €4.19 (see table 7) in 2002 to €5.95 in 200515. The average price of OTC's that have to be sold in pharmacies decreased slightly during the same time period from €8.27 to €8.05.

<table>
<thead>
<tr>
<th>Table 7: Average Price in pharmacies - in €</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Pharmacy only</td>
</tr>
<tr>
<td>Free sales</td>
</tr>
<tr>
<td>GMS Pharmacy</td>
</tr>
<tr>
<td>Median (weighted according to sales turnover)</td>
</tr>
</tbody>
</table>

Source: Insight Health 2006

15 Index comparison 2002 = 100, 2005 = 142
5.2. R&D and Patent situation

The German pharmaceutical industry invested approximately €4.7 billion in R&D in 2006 (see graph 9). This represents an average annual growth rate of 8.53% since 2001.

![Graph 9: Pharmaceutical R&D expenditures (€ bil) – 2001 to 2006](image)

The R&D expenditure levels of the pharmaceutical industry represent approximately 9.5% of the entire R&D expenditures of the German economy. In terms of absolute numbers it is in fourth place, behind the automobile, electronics and chemical industries.

In 2005, 10,452 patent applications, from within and outside Germany, for pharmaceuticals in Germany were published, meaning that the growth level was stable compared to 2004. Interestingly, the total number of German patent owners increased from 1,520 in 2004 to 1,610 in 2005. The portion of German applicant thereby amounted to 15.4%. The major patent applicant is still the USA, however, Germany holds the second rank in an international comparison (see Graph 10).
The number of patents granted amounted to 4,342 (translating to 12% of all patents granted). The German portion amounted to 18.3%

5.3. The GKV Pharmaceutical market

In 2005, approximately 648 million prescriptions were reimbursed by the SHI. The strong decrease in the number of reimbursed prescriptions in 2004 (see Table 8) is a clear effect of recent regulatory changes, including the exclusion of most OTC's. However, the effects of the health care modernisation law, the establishment of the "doctors" fee payable by the patient, as well as the decrease of additional payments for subscription drugs caused a slight increase in the total level of GKV reimbursed prescriptions in 2005 (see table 8).
The largest category was "human pharmaceuticals" with 94.3% of all reimbursed pharmaceuticals (see table 9). Both Phyto-pharmaceuticals and Homeopathic medication experienced a decrease in the share of both sales volume and sales revenues.

Table 9: Development of the market shares debited to the GKV 2003 - 2005 in % and pharmacy selling price

<table>
<thead>
<tr>
<th></th>
<th>Sales Volume</th>
<th>Sales revenues</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2003</td>
<td>2004</td>
</tr>
<tr>
<td>Human medication</td>
<td>91.36</td>
<td>94.26</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>2.02</td>
<td>2.64</td>
</tr>
<tr>
<td>Phyto-pharmacy</td>
<td>4.00</td>
<td>1.34</td>
</tr>
<tr>
<td>Homoeopathic medication</td>
<td>1.12</td>
<td>0.53</td>
</tr>
<tr>
<td>Anthroposophy</td>
<td>0.18</td>
<td>0.12</td>
</tr>
<tr>
<td>Others</td>
<td>1.31</td>
<td>1.11</td>
</tr>
</tbody>
</table>

Source: Insight Health 2006

In terms of sales revenue, the largest category was here also human pharmaceuticals with a total of €24.8 billion, the equivalent of 96.2% market share (see table 9). Phyto-pharmaceuticals made up only 0.41% of total SHI costs due to prescription drugs. However, the smallest was Homeopathic medications with 0.11% translating into €29.1 million costs to the SHI.
5.4. Number of drugs on the German market

Although many critics view the number of drugs available on the German health care market as problematic, it is important to note that the counting method in Germany differs from the international counting method standard.

According to statistics published by the Federal institute for medication and medicinal products (BfArM) in 2006 there were 53,323 drugs that required a permission or registration. However, there are only 8,829 drugs listed in the so called „Rote Liste®“ (“Red List”) (see graph 11), the most comprehensive pharmaceutical listing in German. The reason for this vast difference is that a permission is needed for each different type of drug delivery, even if a permission for the same active ingredients in the same strength has already been given for a similar product. For instance a gel, cream or spray with the same strength and active ingredient need separate permissions. This is unique in Germany.

In addition, „Rote Liste®“ lists only a limited amount of OTCs that are meant for self-medication only. Hence, the quantity of drugs available in Germany cannot be named with absolute security.

5.5. Pharmaceutical Companies
Below is a list of the leading pharmaceutical companies, including phyto-pharmaceuticals and homeopathic products:

3M ESPE AG  
AstraZeneca  
AstraZeneca  
Bayer Pharma GmbH & Co.KG  
Bayer Health Care  
Berlin Chemie  
Boehringer Ingelheim  
Braun Melsung AG  
Bristol-Myers Squibb GmbH& Co. KGaA  
Dermapharm AG  
Fresenius AG  
GlaxoSmithKline GmbH & Co KG  
Hexal Biotech Forschungs GmbH  
Merk KgaA  
Merkle  
Novartis AG  
Pfizer Pharma GmbH  
Ratiopharm  
Roche  
Sanofi-Aventis Deutschland GmbH  
Schering  
Dr. Willmar Schwabe Arzneimittel  
Steigerwald Arzneimittelwerk GmbH

The German pharmaceutical market has gone through a phase of consolidation over the past years. Currently there are no large German pharmaceutical companies, with the last one, Schering, having been taken over by Bayer Health Care in December 2006\(^\text{16}\). All big players are, thus, foreign parties, such as GlaxoSmithKline, Pfizer or Sanofi-Aventis. The remaining German pharmaceutical companies are small or medium sized enterprises, with the leading one being Schwabe.

\(^{16}\) The new name is Bayer Schering Pharma AG
6. The German Medical Devices Market

The German Medical device (MedTech) market is a major contributor to the positive development of the health care economy, as well as being important economic and labour market factors. The German MedTech industry has exhibited some strong advantages compared to other global players. One major advantage is the shorter decision-making and permission-granting times, as well as in the highly qualitative and more economical clinical research. It costs an approximate average €8 to €10 million to bring a new idea the market in Germany. In the USA, the equivalent costs amount to $80 million. However, there is a substantial deficit in Germany, which is rooted in the reformation of the remuneration systems.

MedTech is a dynamic and highly innovative industry. Product cycles are clearly shorter than in the Pharmaceutical sector. More than half of the revenue income is obtained through products that are not older than three years. An average of approximately 7% of revenues is invested in research and development. In comparison, expenditure on research and development amount to 5% of total revenues in highly innovative chemical industries and to 3.8% for the entire processing industry. In fact, 14,700 inventions in medical technology were recorded at the European patent office in Munich, which can be taken as a sign for the innovative strength of the industry.

6.1. Market Development

In 2005, member companies of BVMed’s (Bundesverband Medizintechnik) reported an increase in turnover of 3%, totalling approximately €14.8 billion. In 2004, turnover had increased by 1.5% in the homecare industry. In the preceding years, turnover growth had been significantly stronger at 3.9% in 2003 and 6.5% in 2002. Germany is, thus, lagging far behind the world market development, amounting to an approximate 7%.

6.1.1. Development in Sub-sectors

Especially the medical technical aids sector has been quite restrained. Ostomy and incontinence aids almost stagnated, experiencing a turnover growth of a mere 0.2% compared
to 2004, which had been a particularly bad year for the Medtech aids sector. The considerable decrease in 2004 can be attributed to the restrictive measures of the healthcare reform, particularly in the technical aids sector.

Dressing materials even reported a decrease of 0.1% in 2005 compared to 2004 (totalling just under €1 billion). The development in other sub-sectors was slightly positive. The category “single-use surgical equipment” increased by 2.8% and “single-use devices, intensive care medicine, nursing items” by 4%. This rise in turnover, however, is mainly based on volume growth.

In 2005, the bulk of sales in the medical device market concerned medical devices for intensive and nursing care, which made up over 60% of the market (see graph 12). Incontinence and ostomy care, and dressing materials made up 17% and 15% each.

Graph 12: Medical Device market - Sales Structure 2005

Source: BVMed

6.1.2. Expenditure patterns on Medical Devices

In 2005, expenditures on medical devices amounted to some €19 billion. Of this, €12 billion accounted for the outpatient sector (technical aids, other medical supplies) and €7 billion for the inpatient sector (material costs in hospitals).
The world market for medical technologies totalled some €184 billion in 2003. Of this, the US market contributed €79 billion and the European market approximately €55 billion. Besides the USA and Japan, Germany is the third biggest market worldwide and by far the largest market in Europe. It is about twice as large as the French and three times as large as the Italian and British markets each.

As in previous years, hospitals remained the major buyers of medical devices (46%), followed by specialized traders and pharmacies (38%) as well as other markets (see Graph 13).

**Graph 13: Buyers of medical devices - 2005**

![Pie chart showing buyers of medical devices](chart.png)

Source: BVMed

### 6.2. G-DRGs in the Hospital Sector

Even in the transitional period from a budget system to a fully effective diagnosis related group (DRG) pricing system, an increasingly competition and performance oriented mindset can be observed in the hospitals. 1,740 acute care hospitals were reimbursed on the basis of DRGs in 2005. This represents 95% of those hospitals obliged to adopt the new system.

Since then Germany has evolved into one of the world leaders in the field of DRG reimbursement next to the United States, even though the new prospective payment system
was only introduced as recent as three years ago. The effects of this new system are a reduced length of hospital stays, more efficient process flows in patient care and consolidation processes. The resulting trend of specialising hospitals, mergers and privatisations has already reached the university hospitals.

The performance homogeneity of the DRGs has been further increased with the publication of the DRG catalogue for 2006. The number of DRGS increased to 954, that of supplemental payments to 82, of which many include medical technologies. The basis for the calculation was extended from 133 participating hospitals in the previous year to 214. This will make it easier to compute the actual share of material costs (such as medical device) incurred by each patient.

The payment regulation for new methods of examination and treatment (Neue Untersuchungs- und Behandlungsmethoden, NUB) applied for the first time in 2006. The self-governing bodies charged the Institute for the Reimbursement System in Hospitals (the DRG Institute, InEK) with processing NUB applications filed by hospitals. By the 31st of October 2005, more than 4,000 individual applications had been submitted by the hospitals. Of these, 900 applications – making up 22.5% – were classified as negotiable. Only 26 therapy procedures met the NUB criteria in 2005. The remaining procedures could not be processed in time by InEK and could, thus, be negotiated locally.

The convergence phase provides for a gradual change from the individual budget for hospitalised patients to a national pricing system. Excess DRG performance cases\(^\text{17}\) will not receive payment for the full DRG until 2009. Until then, additional performance case remuneration will be gradually increased. From 2009, DRGs will be paid in full. The debate on the further DRG scope following the end of the convergence phase will begin in 2007 at the latest.

The economic challenges of the new reimbursement system also take their toll on the procurement processes in hospitals. However, a study conducted by the BVMED suggests that the influence of hospital purchasing cooperatives will continue to grow strongly. The share of the medical technology suppliers’ sales to hospital affected through transactions with

\(^{17}\text{above the case volume budgeted for at the beginning of the year}\)
purchasing cooperatives is expected to rise from some 40% today to 90% in 2010. The pooling of negotiating power in hospital purchasing is resulting in an ever increasing pressure on prices, which in turn creates entirely new demands on the sales and marketing activities of the medical device companies.

6.3. Technical Aids

6.3.1. Impact of the Healthcare Reform on the Technical Aids Sector
Even two years after the SHI Modernization Act came into effect, its consequences are felt quite acutely in the medtech aids industry. The health insurance funds’ cost-saving measures affected both the manufacturers and the providers of care involving technical aids. As a result, only approximately €3.3 billion were spent on technical aids in the first three quarters of 2005, representing a share of 3.1% in the total expenditure of Statutory Health Insurance.

6.3.2. Federal Reference Prices
The effects of the first federal reference prices, which have been in force since January 2005, were soon starting to show. As a result, many care providers were only able to provide for adequate patient care by implementing comprehensive rationalization measures. However, even operational or personnel restructuring measures are not always sufficient to maintain the present product and/or service quality in healthcare, unless the patient is prepared to make additional payments. In 2005, the national associations of SHI funds reviewed the federal reference prices already existing.

6.4. Homecare

Homecare is still considered a market with high growth potential. An increasing number of people depend on therapy models provided in their own homes, which is particularly due to demographic changes and multi-morbidity in old age. However, the differentiation between the duties of health and long-term care insurance is not always clear and precise. Nevertheless, this must not lead to a relocation of services into long-term care insurance, thereby increasing cost pressure on the health insurance.
The health insurance funds continue to affect the competition among homecare companies by focusing on the price rather than on quality. On top of unilaterally imposed contractual terms, companies are facing an increasing amount of duties in terms of administration and documentation. This leaves them with a drastically reduced leeway for rendering on-site services based on the patient’s individual needs.

The fact that the focus in German healthcare is predominantly centred on cost-per-item rather than on the overall cost of care per patient case is also evident in the revised pharmaceutical guideline on the reimbursement of oral supplement and tube feeding.

6.5. Trends in Medical Technology

The development of medical technology in the last decades of the 20th century was very dynamic. Synthetic single-use devices, joint replacements, pacemaker technologies or minimally invasive procedures made for a high standard in medical technology.

It is likely that progress will accelerate even more, as a great variety of new technologies is emerging. Examples for these are Tissue Engineering, the development of new “intelligent” materials, integration of telemedical applications in medical technological treatment methods, minimally invasive surgical technologies and nanotechnology. Increasing integration of these technologies results in the development of sophisticated therapies, which often exceed “traditional” limits and areas.

**Tissue Engineering** will allow damaged tissue such as skin, cartilage, bone or blood vessels to be replaced with “engineered” tissue replacements grown on biomaterial “scaffolds”, frequently based on the patient’s own cells or tissues, thereby greatly improving biocompatibility and the chances of better long-term prognosis.

**Cell Therapies** will use human cells as carriers for diagnosis and treatment. One example for this new technology are T-lymphocytes that are “engineered” to carry nanoscale metallic particles to the site of a tumour where they can be activated magnetically or by the use of light, thereby destroying the tumour.
Nanotechnologies offer the possibility to design and construct minimally invasive sensors, e.g. “lab-on-a chip” type devices, that can perform dozens or even hundreds of analyses “in vivo” without the need for the intervention of a laboratory, thereby speeding up diagnosis and monitoring.

Minimally invasive surgical techniques are developing rapidly. The key advantages of such technologies are the decrease in trauma for the patient during treatment and significantly improved recovery times.

Advanced biomedical materials are also revolutionizing medicine. Examples of some recently-developed materials include hydro gels that greatly reduce infection during catheterization and “memory alloys” that can be used to place stents quickly and accurately.

Telemedicine allows the remote and continuous monitoring of patients, e.g. of those with cardiac implants or other conditions, on a routine or one-off basis. An important new development is the so called electronic health card and the so-called e-prescription. To date, e-prescriptions are limited to drugs subject to sale by pharmacists only. In the long term, all prescriptions are to be transmitted electronically. Until then it must be ensured that all care providers are connected to the telematics infrastructure and that the electronic health card takes into account the particularities of the homecare sector.

In terms of growth levels, the BVMed expects that the anticipated improved basic economic conditions will help to promote innovations in medical technology. Although the BMBF forecasted higher annual growth levels for Germany then there are at present (4.1%). The forecasts for EU countries is 5.4% and 6.6% for the USA.
6.6. Medical Technology and Aids Companies

A selection of companies providing MedTech:
3M (incl. Bayer Diagnostics)
Aqua health Care
B.Braun Melsungen
Boso (once Bosch & Soehne)
Custo
Fresenius
GE Healthcare Technology
Hartmann
Hellige
Johnson & Johnson
Lehmann
Likamed
Mediplus
Medka Medizin Produkte
Medtronic
Omron
Philips Medizin System
Physiomed
Schiller
Siemens Medical Solutions
Storz
Zimmer
7. Problems Germany is facing today: Socio-demographic factors

7.1. Demography

Currently, Germany has a population of approximately 82 million. The population density amounts to 230 persons per square kilometre, compared to an EU average of 116. The Federal Republic of Germany has experienced a long-standing downward trend in the population size (see graph 14) and is characterised by a low percentage of young population. This trend is expected to continue in future (see graph 15).

Graph 14: Population development in Germany - 1991 - 2004

Source: Federal statistical office Germany
Life expectancy is rising, which furthers the trend toward an aging population. According to the Federal statistical office, in the near future the percentage of people aged 65 and above will be higher than the percentage of those aged 15 and less.

The Germans’ attitude toward family is directly represented by the low number of marriages and births, with a simultaneous growing rate in divorce rates and high rate of shrinking household sizes. Households with more than 5 persons have become very rare, while the number of one-person households is growing continually. There is an above-average number of one-person households especially in large cities (see graph 16).

---

2050:
The results for the period from 2002 to 2050 are derived from the medium variant of the 10th coordinated population projection. This variant is based on the following assumptions:
1. Fertility will remain constant at 1.4 children per woman for the whole projection period.
2. Life expectancy at birth will increase until 2050 to 86.6 years for girls and to 81.1 years for boys. In 2050, the average life expectancy for 60-year old women will be 28 years, while it will be about 24 years for men of the same age.
3. The balance of external migration of the foreign population will be 200,000 persons each year, while the level of net immigration of the German population will gradually decline from about 80,000 persons in 2002 to zero in 2040.
A further factor contributing to the downward trend in the overall population size is the negative net balance of migration between Germany and foreign countries (see Graph 4).

Graph 17: Migration between Germany and foreign countries: 1992 – 2005

Source: Federal statistical office Germany
7.2. Health and Diseases

Total costs increased nearly threefold between 2002 and 2004, from €89,684 million to €224,941 million. The largest increase in costs was felt in the category “diseases of musculoskeletal system and connective tissue” (175%) from €8,876 to €24,475, followed by “diseases of oral cavity, salivary glands and jaws” (102%), and “mental and behavioural disorders” (98%) (see diagram 18).

The largest reduction in the cost structure was observed in the category “pregnancy, childbirth and the puerperium”, which fell by 14.3%, followed by “diseases of the eye and adnexa” (12.6%), and “asthma, acute severe” (8.5%) (see diagram 18).

In terms of total costs, in 2004 the largest expenditures went towards “diseases of the circulatory system” (€35,270), followed by “diseases of the digestive system” (€33,270) and “diseases of the musculoskeletal system and connective tissue” (€24,475) (see diagram 18).
Graph 18: Direct health costs according to type of disease: 2002 and 2004

Source: Federal statistical office Germany
Overall, 23% of all death causes were directly attributed to heart conditions (see graph 19). The leading cause was “chronic ischemic heart disease” (9.8%), followed by “acute myocardial infarction” (7.4%) and “heart failure” (5.8%).

**Graph 19: Leading causes of death – 2005**

![Graph showing leading causes of death with percentages for different causes including chronic ischemic heart disease, acute myocardial infarction, heart failure, and others.]

Source: Federal statistical office Germany

### 7.3. Reasons for increasing health costs

Two main causes for the cost explosion in the health care sector are the progress in MedTech and in demography. As shown above, Germany is facing an ever-aging population with a growing cost-burden on the shrinking percentage of the younger population.

Additionally, there are some institutional issues that lead to higher expenditures. For instance, higher earners can choose to opt out of the SHI and buy private insurance. As a consequence, payments that would otherwise have been made into the SHI now flow to private health insurances. Also, the option to make use of benefits in kind reduces the motivation on the part of the recipient to behave cost-consciously. A large percentage of costs is incurred through a
wide spread practice to seek a second or even third opinion. This issue of double examination is in the focus of politicians who are trying to eradicate it.

8. Upcoming changes

8.1. Integrated medical care

In an attempt to improve the quality, productivity and efficiency of the German health care in light of the current and future caveats, alternative structures are being turned to. In 2004, a new law was passed, the “Gesetz zur Modernisierung der gesetzlichen Krankenversicherung (GMG)” (“The law regarding the modernisation of the Statutory Health Insurance”). The move to, what is referred to as “Integrierte Versorgung (IV)” (“Integrated Medical Care”) is a new direction in the German health care politics. The GMG lays the legal foundation for it. IV is also called the medical care model of the future. The basic idea behind it is to combine the main building blocks of the health care system, namely, ambulatory care, in-patient care and rehabilitation. Through a move to network-like structures, including all medical health care and service providers, the quality and efficiency within the system is to be improved.

8.2. Medizinische Versorgungszentren (MVZs) (“the medical care centres”)

A new and major part of GMG was the legal basis for the introduction of the “Medizinische Versorgungszentren (MVZs)” (“the medical care centres”). These are hubs where medical care is to be provided from one point. Unlike in most cases, today patients still need to go to various doctors or medical institutions that are usually placed at different locations. The idea behind MVZs is to provide centres where patients may receive all their required medical diagnostics, treatments, medication and medical aids in one place. An essential criteria for MVZs is that it needs to include a variety of different medical fields, where SHI affiliated physicians and other medical professionals cooperate.

An important change in health care politics is, that within these structures the strict differentiation between ambulatory and in-patient care is being softened somewhat. Furthermore, these structures seek to increase the competition among medical service providers and, thereby, increase efficiency within the system.
The aim is to coordinate diagnostics and therapies within the MVZ, and with external institutions, such as hospitals. Also, due to the combined financial strength of the MVZ members, acquisitions may be made that an individual physician can not afford, or, via a contractual agreement with a hospital, MVZ members may use medical equipment for diagnostic purposes. Thereby, time and costs that occur through executing the same diagnostics more than once are sought to be saved and double prescriptions are to be prevented. Decision-making and, thus, reaction to a medical need are to be shortened and the scope of therapeutic possibilities for the individual physician is to be increased.

In the third quarter of 2006, there were 562 such MVZs in Germany, where 2,183 physicians operated. Most doctors in this new structure were general practitioners, cardiologists and surgeons. The average MVZ size amounts to 4 doctors\(^{19}\). The aim of the political system is to develop larger sized MVZs. The leading MVZ-regions are Bavaria, Berlin, Lower Saxony and Hessen.

\(^{19}\) www.kbv.de/themen/7178.html
9. The German Biotech sector

The commercial development of Biotechnology in Germany began somewhat later than elsewhere. The German Biotech industry expanded only after the amendment of the genetic engineering law in 1993 and the initiation of the “Bio Region” competition of the Federal Ministry for education and research (Bundesministerium für Bildung und Forschung, BMBF). However, the world-wide slowdown of economic development that followed the bubble burst of the, so called, new economy at the turn of the century, introduced a consolidation phase in Germany.

The German Biotech sector consists of 480 dedicated Biotech companies20, of which only 2.7% (14 companies) were publicaly listed in 2005. The numbers of newly found companies and insolvencies are rather balanced. In 2005, 15 new companies were established compared to 19 companies that faced insolvency. These 480 dedicated Biotech firms generated approximately €1.54 billion in revenue income in 2005, and allocated approximately €714 million to research and development.

In addition to those dedicated firms, there are a further 59 enterprises whose activities also, but exclusively, consist of Biotechnology. These companies include big pharma, chemical companies and seed manufacturers.

The majority of German Biotechnology companies (84%) are active in the human health care and medicine sector, 19% in veterinary Biotechnology, 13% in the white Biotechnology sector (industrial Biotechnology). Only less than 10% focus on a range of agricultural topics.

9.1. Age Structure

With an average of 35 new start-ups annually, the German Biotech industry is still in a phase of rapid expansion. However, it is still a very young industry where the average age of the dedicated Biotechnology enterprises amounted to only 6.9 years for the end of 2005. Nearly a

---

20 Meaning companies focus exclusively or largely on Biotechnology
fifth of the companies (19.2%) were created prior to 1995 (see graph 20). This indicates a significant number of enterprises that have already reached a certain level of maturity.

Graph 20: New Biotechnology firms

Source: Biotechnologie.de

The German set-up boom began only once the “Bio Region” competition was initiated by the BMBF (see Graph 20). Half of all existing dedicated Biotech enterprises were created between 1997 and 2001.

9.2. Bio regions

In many areas, Biotech cluster and crystallization points for specialized technologies were formed, largely in regions that took part in the 1995 BMBF “Bio Region” competition. Additionally, different regions, cities and municipalities have created a variety of incentives aimed at attracting Biotech enterprises.

The highest number of Biotech enterprises can be found in the Bavaria, where there are 94 fully dedicated Biotechnology companies and 8 that concentrate partly on Biotech. In second place is Baden-Württemberg (77 dedicated and 3 companies that concentrate partly on Biotechnology), followed by North Rhine-Westphalia (55 dedicated and 11 companies that concentrate partly on Biotechnology). However, if one views Berlin and Brandenburg as one cluster, it would be the second largest cluster in Germany with 84 dedicated and 3 companies that concentrate partly on Biotechnology. When viewing Berlin as a single cluster it is the
fourth biggest one, with 50 dedicated and 1 company that concentrate partly on Biotechnology (see graph 21).

**Graph 21: Distribution of the 480 dedicated Biotech companies in Germany.**

The symbol size increases according to the number of enterprises in any one place\(^{21}\). The clusters are very evident on this map.

\(^{21}\) The areas are defined according to the postal code
9.3. Areas of Biotechnology

German Biotechnology enterprises concentrate mainly on the so called red Biotechnology sectors, which concerns human health care (see Graph 22). According to a recent research carried out by the German Biotechnology Association (DIB) over 80% of all dedicated Biotechnology enterprises worked in this industry. Just under one fifth of all companies concentrated on animal health. In the specified research areas, over 13% of companies focus on industrial Biotechnology, while close to 10% on agriculture. Over 60% of the enterprises use non-specific or other research methods, which depicts the interdisciplinary characteristic and wide range of possible application of Biotechnology.

Graph 22: Segments of the Biotech- Companies in Germany (concentrating only or mainly on Biotechnology)\(^{22}\)

- Health care: 83.30%
- Animal health: 19.20%
- Agrar: 9.60%
- Industrial biotech: 13.20%
- Unspecified Research area: 35.00%
- Others: 28.60%

Source: DIB 2006

The majority of procedures used are Genomic and Proteomic based methodologies. Furthermore, nearly 50% of companies use cell and tissue samples. Approximately a quarter makes use of system-biological procedures and a fifth moves among the frontiers between Biotechnology and Nanotechnology (see graph 23).

\(^{22}\) Multiple nomination possible
At the same time, most companies pursue several business strategies simultaneously. The most common business strategy is offering companies to outsource their research facilities (76.5%). Another very popular strategy is the offering of product and process development (nearly 62%) (see Graph 24).

Source: DIB 2006
9.4. Sources of Equity

Revenue Streams
In mid-2006, there were 119 genetically manufactured medications on the market, which are based on 85 different active substances. Of these, 17 stem from German production. These drugs accounted for approximately 10% of the total German pharmaceutical market, amounting to approximately €2.06 billion in sales revenues (see table 10). Furthermore, in 2005, the Biotechnology-based diagnostics market produced an estimated €600 millions in revenues.

Table 10: Revenue stream of genetic engineered medicine in the German pharmaceutical market (mil €)

<table>
<thead>
<tr>
<th>Category</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-diabetics</td>
<td>527</td>
<td>583</td>
<td>664</td>
<td>657</td>
<td>687</td>
</tr>
<tr>
<td>Immunisation and Sera</td>
<td>222</td>
<td>211</td>
<td>199</td>
<td>188</td>
<td>177</td>
</tr>
<tr>
<td>Immun-modulators</td>
<td>352</td>
<td>410</td>
<td>489</td>
<td>572</td>
<td>609</td>
</tr>
<tr>
<td>Hormones</td>
<td>142</td>
<td>177</td>
<td>191</td>
<td>150</td>
<td>155</td>
</tr>
<tr>
<td>Others</td>
<td>172</td>
<td>250</td>
<td>283</td>
<td>379</td>
<td>427</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,415</td>
<td>1,631</td>
<td>1,826</td>
<td>1,946</td>
<td>2,055</td>
</tr>
</tbody>
</table>

Source: VFA (2006)

The highest increase in revenues can be seen in the category “others”, where an average annual increase of nearly 30% was achieved. The only category that experienced a decrease was “immunisation and sera”.

Venture Capital and other public sources
Since the subject of Venture Capital will be outlined in more detailed in section 10, only a very brief overview will be given at this point. Venture Capital still represents a substantial financial resource for the German health care related enterprises. Although 2005 saw a slight reduction of the moneys raised through public offerings compared to 2004, German Biotechnology companies were still able to raise €163 million (see table 11).

Table 11: Equity raised through the stock exchange by German Biotech companies (mil €)

<table>
<thead>
<tr>
<th>Category</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public offerings</strong></td>
<td>23</td>
<td>1</td>
<td>3</td>
<td>186</td>
<td>163</td>
</tr>
</tbody>
</table>

Source: DIB 2006
Other sources of income included nearly €50 million of Government funding on all levels (national, federal and municipal).

9.5. Patent situation
Germany is the leading European country for patent registration for pharmaceuticals based on Biotechnology. Between 1995 and 2005 patents in this field more than doubled (see table 12)

<table>
<thead>
<tr>
<th></th>
<th>1995</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>352 (55 %)</td>
<td>597 (43 %)</td>
</tr>
<tr>
<td>Germany</td>
<td>65 (10 %)</td>
<td>157 (11 %)</td>
</tr>
<tr>
<td>Japan</td>
<td>28 (4 %)</td>
<td>162 (12 %)</td>
</tr>
<tr>
<td>UK</td>
<td>41 (6 %)</td>
<td>78 (6 %)</td>
</tr>
<tr>
<td>France</td>
<td>41 (6 %)</td>
<td>81 (6 %)</td>
</tr>
<tr>
<td>Others</td>
<td>118 (19 %)</td>
<td>300 (22 %)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>645 (100 %)</strong></td>
<td><strong>1,375 (100 %)</strong></td>
</tr>
</tbody>
</table>

Source: German Ministry for Patents (2006)
### 9.6. Selection of German Biotech companies according to category

<table>
<thead>
<tr>
<th>Pharmaceutical Biotechnology</th>
<th>Genomics/ Bioinformatics</th>
<th>Proteomics</th>
<th>DNA Analysis</th>
<th>Bioinstruments</th>
<th>Bioreactors / Cell Culture Devices</th>
<th>Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intendis GmbH</td>
<td>LION Bioscience AG</td>
<td>Axaron Bioscience AG</td>
<td>ATG: biosynthetics GmbH</td>
<td>Afectis Pharmaceuticals AG</td>
<td>8Sense biognostic AG</td>
<td>Bayer Healthcare AG</td>
</tr>
<tr>
<td>BIOLOG Life Science Institute Forschungslabor und Biochemica</td>
<td>AGOWA Gesellschaft für molekularbiologische Technologie</td>
<td>Retro-Tech Gesellschaft für retrovirale Technologie mbH</td>
<td>Institut für Medizinische Molekular-Diagnostik GmbH</td>
<td>IonGate Biosciences GmbH</td>
<td>Adaldis Deutschland GmbH</td>
<td>BIOLOG Life Science Institute Forschungslabor und Biochemica</td>
</tr>
<tr>
<td>Aventis Research and Technologies GmbH &amp; Co. KG</td>
<td>GBF German Research Centre for Biotechnology</td>
<td>GBF German Research Centre for Biotechnology</td>
<td>Congen Biotechnologie GmbH</td>
<td>Roche Diagnostics GmbH</td>
<td>Autoimmun Diagnostika GmbH</td>
<td>IMGM Laboratories GmbH</td>
</tr>
<tr>
<td>Boehringer Ingelheim GmbH Corporate Division</td>
<td>EUROGENTEC Proteomics GmbH</td>
<td>IPF PharmaCeuticals GmbH</td>
<td>4base lab GmbH advanced molecular analysis</td>
<td>Nanofilm Technologie GmbH</td>
<td>Aqua-Tek Biotechnologie GmbH</td>
<td>Boehringer Ingelheim microParts GmbH</td>
</tr>
<tr>
<td>Bayer Healthcare AG</td>
<td>Eppendorf AG</td>
<td>Microbionix GmbH</td>
<td>Genotype GmbH</td>
<td>november AG</td>
<td>Ars Arthro AG</td>
<td>BRAHMS Aktiengesellschaft</td>
</tr>
<tr>
<td>Grandis Biotech GmbH</td>
<td>Genotype GmbH</td>
<td>NeuroProfile GmbH</td>
<td>humatrix AG</td>
<td>PharmaInformatic</td>
<td>Celonic GmbH</td>
<td>In vitro Biotec GmbH</td>
</tr>
<tr>
<td>Faustus Forschungs Compagnie Translational Cancer Research GmbH</td>
<td>Institute for cell- and organ simulation GmbH</td>
<td>Proteome Sciences R&amp;D GmbH &amp; Co. KG</td>
<td>IIT an der Universität Bielefeld GmbH</td>
<td>RINa - Netzwerk RNA-Technologien GmbH</td>
<td>Hybrid Organ GmbH</td>
<td>BRAIN Biotechnology Research and Information Network AG</td>
</tr>
<tr>
<td>iOnGen AG</td>
<td>2D-CellVision</td>
<td>Xantos AG</td>
<td>Eppendorf AG</td>
<td>Miltenyi Biotec GmbH</td>
<td>Zellwerk GmbH</td>
<td>BioTeZ Berlin-Buch GmbH</td>
</tr>
<tr>
<td>Roche Diagnostics GmbH</td>
<td>RZPD Deutsches Ressourcenzentrum für Genomforschung GmbH</td>
<td>RZPD Deutsches Ressourcenzentrum für Genomforschung GmbH</td>
<td>vertis Biotechnologies AG</td>
<td>Xantec Analysensysteme</td>
<td>MERLIN Gesellschaft für mikrobiologische Diagnostika mbH</td>
<td></td>
</tr>
</tbody>
</table>
10. The German VC Market

After the upswing of the late 90's the German private equity market was subject to a consolidation period from 2001 to 2003. During this time the market was confronted with continuous problems in fund raising, quantitative and qualitative changes of investment placements as well as the execution of exits. In 2004 the first signs of a market recovery showed, which continued in 2005. In fact, 2005 saw the introduction of many legal and administrative measures that pervade legal security, leading to the increase of capital raised by (new) equity funds, which in turn were able to invest in more companies, thus, increasing their total portfolio volume (see graph 25).

Graph 25: Total volume of Venture Capital portfolio in € ‘m – at start and at end of year

In 2005, the private equity market reached a volume of €3 billion (see table 13) which meant a decrease of approximately 19% compared to 2004. This is mainly due to a lower amount of very large buy-outs. However, the number of total companies that acquired funding rose from 950 to 983, which signals an increasing demand of private equity funding.

Table 13: Total investment placements according to investment category - € million
With regards to VC funding, a total of 901 companies received funding in 2005 compared to 890 in 2004 (see table 14). Although most sectors experienced a decrease in the total amount of companies, especially turn-around financing (39%), two sectors saw an increase of 17% (bridge financing) and 6% (expansion capital).

Table 14: Number of companies that received Venture Capital - according to categories

<table>
<thead>
<tr>
<th></th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seed</td>
<td>94</td>
<td>272</td>
<td>103</td>
<td>95</td>
<td>28</td>
<td>26</td>
<td>20</td>
</tr>
<tr>
<td>Start-up</td>
<td>544</td>
<td>742</td>
<td>732</td>
<td>639</td>
<td>324</td>
<td>330</td>
<td>325</td>
</tr>
<tr>
<td>Expansion</td>
<td>559</td>
<td>896</td>
<td>888</td>
<td>805</td>
<td>441</td>
<td>490</td>
<td>521</td>
</tr>
<tr>
<td>Replacement</td>
<td>19</td>
<td>21</td>
<td>21</td>
<td>10</td>
<td>6</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Turnaround</td>
<td>12</td>
<td>39</td>
<td>70</td>
<td>49</td>
<td>18</td>
<td>23</td>
<td>14</td>
</tr>
<tr>
<td>Bridge</td>
<td>65</td>
<td>108</td>
<td>63</td>
<td>40</td>
<td>8</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Venture Capital</td>
<td>1293</td>
<td>2078</td>
<td>1877</td>
<td>1638</td>
<td>825</td>
<td>890</td>
<td>901</td>
</tr>
</tbody>
</table>

Source: BVDKG

Although the private equity sector is still favouring the Buy-Out market, Venture Capital was able to increase its total funds allocated – from €1,079 million to €1,272 million. This was also reflected in the total amount of VC funding allocated (see graph 26).
Although the main bulk of total investment placement was still allotted to the Buy-out segment, it experienced a strong decrease (58.2% in 2005 and 71.3 % in 2004). Simultaneously, other sectors experienced increases. For example, the seed and start-up category received 10% in 2005, slightly up from 9.4% in 2004. However, the largest increase was felt in the so called expansion capital category, which nearly doubled its share from 16.2% to 31.2% in 2005.

In terms of Venture Capital only, the two leading categories in 2005 were start-up (23.5% or €298 mil) and expansion capital (74.7% or €950 million) (see table 15 and graph 27). When analysing these figures, a clear trend towards expansion capital becomes apparent.
Table 15: Venture capital financing - percentage share of each sub-category

<table>
<thead>
<tr>
<th>Sub-category</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seed</td>
<td>7.8%</td>
<td>10.4%</td>
<td>6.2%</td>
<td>5.6%</td>
<td>3.8%</td>
<td>2.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Start-up</td>
<td>30.5%</td>
<td>32.6%</td>
<td>35.3%</td>
<td>35.5%</td>
<td>37.5%</td>
<td>30.7%</td>
<td>23.5%</td>
</tr>
<tr>
<td>Expansion</td>
<td>41.4%</td>
<td>42.0%</td>
<td>49.5%</td>
<td>51.7%</td>
<td>52.8%</td>
<td>56.7%</td>
<td>74.7%</td>
</tr>
<tr>
<td>Replacement</td>
<td>16.1%</td>
<td>11.1%</td>
<td>3.7%</td>
<td>2.6%</td>
<td>1.7%</td>
<td>0.8%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Turnaround</td>
<td>0.5%</td>
<td>1.1%</td>
<td>2.7%</td>
<td>3.2%</td>
<td>3.6%</td>
<td>1.2%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Bridge</td>
<td>3.7%</td>
<td>2.7%</td>
<td>2.6%</td>
<td>1.3%</td>
<td>0.6%</td>
<td>8.6%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

Source: BVDKG

Graph 27: Subcategories of Venture capital financing - € million

Source: BVDKG
10.1. Investment placements according to industry sectors

During 2005, the leading industries in terms of investment placement acquirement were communication technology with 11.9%, consumer goods with 11.2%, other services with 9.6% and machine/equipment construction with 9.3%. The combined health care industries made up a total of 11% (See Graph 28) or nearly €300 million (see graph 29).

Graph 28: Percentage of Health-care categories that received investment placements

Source: BVDKG
The average investment per company in all sectors increased from just over €0.8 million in 1995 to €3 million in 2005 (see graph 30). In 2005, medical health-care companies received an average of €5 million.
Although the medical health-care group is the smallest health care company category\textsuperscript{23}, it has been able to attract substantial VC funding. In fact, in 2004, this group accounted for only 0.5\% of all companies that received private equity funding, but was able to attract 10.4\% of total investments, with an average of over €20 million per company. The category “pharmaceutical” is viewed similarly favourable, having received 5.8\% of all private equity placements, while constituting for only 0.7\% of total companies.

\subsection*{10.2. Regions}

Although the portion of investments in Germany decreased from 72.3\% in 2004 to 70.2\% in 2005 (see table 16), the German equity market remains still strongly national. The portion of the EU-wide investments remained relatively constant at 27.0\% compared to 25.1\% in 2004. IN 2005, only 2.8\% of investments were made outside the European Union, compared to 2.6\% in 2004.

\textsuperscript{23}In 2005 it made up 0.3\% of the total number of companies that received investment placements.
When viewing this data from the aspect of total number of companies that received investment placements, the market share of European and non-European has been fairly equal since 1999 (see graph 31). Nonetheless, prior to 1999, it seems that there was a preference towards companies from European origin.

**Graph 31: VC investment outside Germany - No of companies as a % of total companies that received investment placements**

In monetary terms, the amount of investment outside Europe has substantially decreased since 2001, when it reached a peak of nearly €460 million (see graph 32). 2005 saw a near 16% decrease compared to the previous year, barely reaching €85 million.
Graph 32: VC investment outside Europe - € million

Source: BVDKG

10.3. Exits

2005 saw a total of 717 exits, of which the majority were sales related. All exits, including total losses, amounted to €1,863.5 millions in 2005 compared to €1,481.4 millions in 2004 (see table 17).

Table 17: Exits in € million - 1999 to 2005

<table>
<thead>
<tr>
<th></th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial sale</td>
<td>251</td>
<td>336.4</td>
<td>459</td>
<td>137.1</td>
<td>169</td>
<td>151.7</td>
<td>797.68</td>
</tr>
<tr>
<td>Total Sale</td>
<td>358.9</td>
<td>693.3</td>
<td>722</td>
<td>1,053.5</td>
<td>321.2</td>
<td>926.2</td>
<td>874.26</td>
</tr>
<tr>
<td>Total loss</td>
<td>162.1</td>
<td>232.1</td>
<td>684</td>
<td>941.2</td>
<td>330.2</td>
<td>403.5</td>
<td>191.51</td>
</tr>
<tr>
<td>Total exits</td>
<td>772.1</td>
<td>1,261.9</td>
<td>1,855.00</td>
<td>2,131.80</td>
<td>820.4</td>
<td>1,481.40</td>
<td>1,863.45</td>
</tr>
</tbody>
</table>

Source: BVDKG

Due to end of the private equity market’s consolidation phase in 2004, a clear drop in total losses could be felt from 2004. Total losses sunk from 40% in 2003, to 27% in 2004 and 10% in 2005 (see Graph 33).
Graph 33: Total Write offs as a percentage of total exits

Source: BVDKG

Indeed, in terms of average loss per company, 2005 saw the lowest figures since 1999 (see table 18).

Table 18: Exits in € million - 1999 to 2005

<table>
<thead>
<tr>
<th></th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial sale</td>
<td>1.67</td>
<td>1.13</td>
<td>1.24</td>
<td>0.32</td>
<td>1.13</td>
<td>1.00</td>
<td>3.63</td>
</tr>
<tr>
<td>Total Sale</td>
<td>1.38</td>
<td>1.93</td>
<td>1.94</td>
<td>3.45</td>
<td>2.01</td>
<td>4.47</td>
<td>2.97</td>
</tr>
<tr>
<td>Total loss</td>
<td>1.00</td>
<td>1.09</td>
<td>1.54</td>
<td>1.92</td>
<td>1.30</td>
<td>1.60</td>
<td>0.96</td>
</tr>
</tbody>
</table>

Source: BVDKG

Furthermore, in 2005 average partial sales experienced its highest level in over 10 years with €3.63 million per company. Although total sales experienced a drop in 2005, it still managed to raise an average of nearly €3 million per company.
VC Company’s

German VC companies who invest both in Biotechnology and/or Health care (including medical device) and in Israel:

Global LifeScience Ventures GmbH
SCHOTT AG
STAR Ventures
Siemens Venture Capital GmbH
smac partners GmbH

The following companies invest generally in companies whose origin is of non-German countries:

One Equity Partners Europe GmbH
AutoVision GmbH -venture-
## 11. Appendix: Industry and trade associations

<table>
<thead>
<tr>
<th>Name</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotechnologie im Verband Forschender Arzneimittelhersteller e.V.</td>
<td>VFA Bio</td>
</tr>
<tr>
<td>Biotechnologie-Industrie-Organisation Deutschland e.V.</td>
<td>BIO Deutschland</td>
</tr>
<tr>
<td>Bundesverband der Arzneimittelhersteller e.V.</td>
<td>BAH</td>
</tr>
<tr>
<td>Bundesverband der Deutschen Industrie</td>
<td>BDI</td>
</tr>
<tr>
<td>Bundesverband der Pharmazeutischen Industrie e.V.</td>
<td>BPI</td>
</tr>
<tr>
<td>Bundesverband Medizintechnologie</td>
<td>BVMed</td>
</tr>
<tr>
<td>Bundesvereinigung Deutscher Apothekerverbände</td>
<td>ABDA</td>
</tr>
<tr>
<td>Deutsche Gesellschaft für Biomedizinische Technik im VDE</td>
<td>DGBMT</td>
</tr>
<tr>
<td>Deutsche Industrievereinigung Biotechnologie</td>
<td>DIB</td>
</tr>
<tr>
<td>Deutsche Industrievereinigung Biotechnologie</td>
<td>DIB</td>
</tr>
<tr>
<td>Deutsche Krankenhausgesellschaft</td>
<td>DKG</td>
</tr>
<tr>
<td>Fachverband Biomedizinische Technik e.V.</td>
<td>Fbmt</td>
</tr>
<tr>
<td>Fachverband Elektromedizinische Technik</td>
<td>ZVEI</td>
</tr>
<tr>
<td>Gesellschaft für Chemische Technik und Biotechnologie e.V.</td>
<td>DECHEMA e.V.</td>
</tr>
<tr>
<td>Kassenärztliche Bundesvereinigung</td>
<td>KBV</td>
</tr>
<tr>
<td>Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.</td>
<td>MeTNet</td>
</tr>
<tr>
<td>Medizin Technik Netzwerk NRW e.V.</td>
<td>Svitg</td>
</tr>
<tr>
<td>Spitzenverband Informationstechnologie im Gesundheitswesen</td>
<td>VCI</td>
</tr>
<tr>
<td>Verband der Diagnostica-Industrie</td>
<td>VDGH</td>
</tr>
<tr>
<td>Verband der Universitätsklinika Deutschlands</td>
<td>VUD</td>
</tr>
<tr>
<td>Verbund biowissenschaftlicher und biomedizinischer Gesellschaften e.V.</td>
<td>VDI</td>
</tr>
<tr>
<td>Verein deutscher Ingenieure e. V.</td>
<td>VBU</td>
</tr>
<tr>
<td>Vereinigung deutscher Biotechnologie-Unternehmen</td>
<td>ZMT</td>
</tr>
<tr>
<td>Zentralvereinigung medizin-technischer Fachhändler, Hersteller, Dienstleister und Berater e.V.</td>
<td>ZMT</td>
</tr>
</tbody>
</table>