

Medicinal Products and Health Care in Austria  
Facts 2009/Edition 2011

09

# FACTS & FIGURES

## EDITION 2011



Association  
of the Austrian  
Pharmaceutical  
Industry

**PHARMIG**

# FACTS & FIGURES

Medicinal Products and Health Care in Austria  
Facts 2009/Edition 2011

**PHARMIG**

The logo for PHARMIG, featuring the word "PHARMIG" in a bold, blue, sans-serif font. A thin blue horizontal line is positioned below the text, starting under the 'P' and ending under the 'G'.

In any case the German version prevails.

Please note that numbers have been presented in German format.

### **Currency**

All indicated values are stated in Euros. Sum totals relating to the national economy are generally indicated in millions of Euros. Individual amounts and microeconomic data are generally stated in Euros.

### **Reference periods**

Wherever possible, comparisons are made for the period 1995 through 2009.

### **Gender neutrality**

All terms referring to individuals are generic and refer to both genders.

### **Laws and technical terms**

Quotations and technical terms were inserted between parentheses.

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# PHARMIG AT A GLANCE

Pharmig, the Association of the Austrian Pharmaceutical Industry, was founded in 1954 with the mission to represent the pharmaceutical industry operating in Austria. Today, the 119 member companies (status of April 2011) supply almost 100 percent of the Austrian pharmaceutical market. Pharmig is politically independent, and all officials serve in an honorary capacity.

Supreme decision-making body is the operating management board who is elected for a four year term of office. The management is headed by a president, two vice presidents and the operating secretary general. Member companies are being represented by delegates in specific counties. Furthermore there are a number of expert committees and working teams that are actively involved in the association work.

Located in Vienna, Pharmig sees itself as central institution representing the topics of the Austrian pharmaceutical industry and as a driving force for quality and supply guarantee of the healthcare system considering the quality of location.

Pharmig is seen as professional player as well as participant and contributes to guarantee the availability of innovative and established medicinal products for the Austrian patients.

DEAR READERS,

Preface



Image © sticht.fotografie.at

The 2009 figures underscore the formidable contribution the pharmaceutical industry has made to reducing costs in healthcare. Take the price of drugs for starters: a theoretical package of drugs that cost 10 euros in 1995 now costs only 8.20. The consumer price index, in contrast, has moved in exactly the opposite direction. Secondly, a glance at the reimbursement market reveals that whereas spending on medicinal products rose by 7.5% from 2007 to 2008, this increase amounted to only 1.7% from 2008 to 2009.

Two factors contributed towards this: the Pharmaceutical Framework Agreement as well as the expiration of drug patents. And without wanting to anticipate next year's issue, we can say that this trend is set to continue.

In its characteristic manner and with the accustomed quality, this issue of "Facts and Figures" provides you with data on the key areas of Austrian healthcare.

Sincerely,

A handwritten signature in black ink, appearing to read 'Huber', written in a cursive style.

Dr. Jan Oliver Huber  
Pharmig Secretary General

## 1

## ECONOMIC KEY DATA

1.1  
GENERAL FACTS & FIGURES 2008/2009

The population of Austria in 2009 was 8.363.040. 99% are protected by one of the 22 social insurance institutions (status 2009). Social expenditures in total amounted to Euro 77.31 billion in 2008.

SOCIAL EXPENDITURES* ACC. TO FUNCTION IN 2008	EURO MILLIONS	PERCENT
Age	32.556,98	42.1
Illness/health care	20.214,46	26.1
of which sickness benefits	453,77	0.6
of which continued payment of wages during illness	2.511,04	3.2
of which in-patient care	8.834,09	11.4
of which out-patient care	7.732,58	10.0
of which prevention of illness/rehabilitation	636,36	0.8
of which other benefits in cash/in kind	46,92	0.1
Family/children	7.992,66	10.3
Surviving dependants	5.463,00	7.1
Invalidity/disability	5.997,77	7.8
Unemployment	3.884,41	5.0
Habitation and social exclusion	1.204,97	1.6
<b>TOTAL</b>	<b>77.314,25</b>	<b>100</b>

Source: Statistics Austria

\* The social expenditures in the functional breakdown are the sum of the social benefits, excluding payments to other systems (re-routed social contributions and other transfers) and other expenditures (administration costs and other expenditures that cannot be allocated).

Social expenditures amounted to Euro 77.31 billion in 2008.

## HEALTH CARE FINANCING

	2008		2009	
	Euro Mill.	Percent	Euro Mill.	Percent
Public health care financing	22.630	77.2	23.536	77.7
In-patient care*	10.078	34,4	10.564	34,9
Out-patient care	5.296	18,1	5.529	18,2
Long-term care at home**	1.806	6,2	1.961	6,5
Ambulance and emergency medical services	283	1,0	303	1,0
Pharmaceutical products, medical equipment	3.229	11,0	3.136	10,3
Prevention and public health services	445	1,5	439	1,4
Health care administration: State incl. social insurance	665	2,3	661	2,2
Public investments	827	2,8	945	3,1
Private health care financing	6.698	22,8	6.772	22,3
In-patient care*	1.642	5,6	1.654	5,5
Out-patient care	1.784	6,1	1.814	6,0
Pharmaceutical products, medical equipment	1.818	6,2	1.867	6,2
Insurance of health care	370	1,3	377	1,2
Investments (private)	771	2,6	785	2,6
Non-profit private organisations***	278	0,9	239	0,8
Services provided by company physicians	35	0,1	36	0,1
<b>TOTAL</b>	<b>29.328</b>	<b>100</b>	<b>30.308</b>	<b>100</b>

\* Includes in-patient health care services in nursing homes.

\*\* Public spending for long-term care at home also includes federal and provincial nursing allowances.

\*\*\* Includes expenditures of non-profit private organisations and other health-related services.

Source: Statistics Austria

The expenditure on health care has been retrospectively updated by Statistics Austria back to 1990 and is drawn from "System of Health Accounts" (SHA) from ongoing health care expenditure and investments in the area of health.

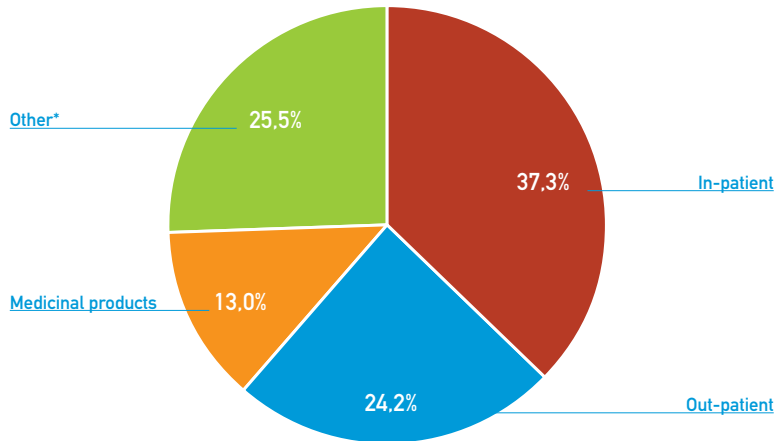
In 2009, it was a total of around 30,31 billion Euro, corresponding to a GDP share of 11%. When broken down into public and private expenditure on health care, we see that more than three quarters of the expenditure was funded by public funds. In the period between 1990 and 2009, expenditure on health care rose on average by 5,3% each year.

An international comparison of health care expenditures can be found under item "1.2 Comparative Health Care Expenditures". Due to national differences in the health care systems, however, and in view of varying data availability in the individual countries, international comparisons can only be indicative.

The percentages indicated here show the share in total expenditure on health care.

In 2009, health expenditure in Austria amounted to 11% of GDP.

## HEALTH CARE EXPENDITURE 2009



\* med. products; equipment; insurance benefits; emergency medical services; public health services; investments; training and education in health care, etc.

Source: IPF

According to current calculations, the pharma-ratio thus amounts to 13.02% (share of overall expenditure on medicinal products in health care spending in %).

## EMPLOYEES IN THE HEALTH CARE SYSTEM (SELECTION) 2009

NUMBER

Practicing physicians	43.742
General practitioners	12.979
of whom solely employed physicians	5.283
Medical specialists	19.219
of whom solely employed physicians	9.134
Dentists	4.619
of whom solely employed physicians	515
Physicians in training	6.925
of whom solely employed physicians	6.925
Pharmacy employees	14.600
Pharmacists, employed or self-employed	5.160
Qualified staff	5.690
Other employees	3.750
Medical experts in hospitals	104.408
Physicians	21.752
Nursing staff	82.656

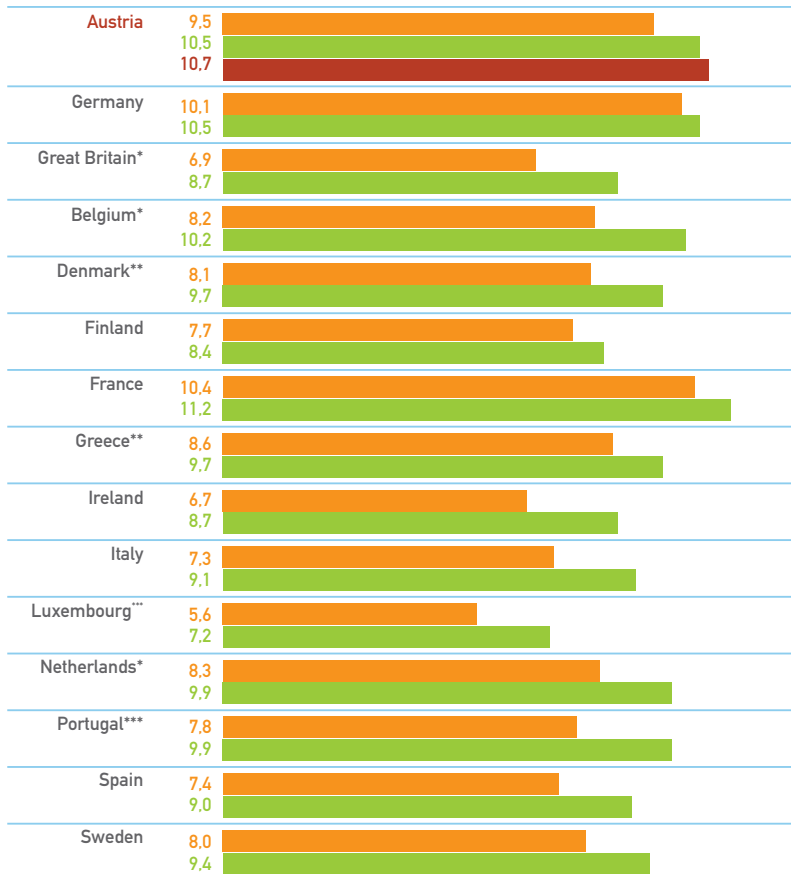
Source: Statistics Austria, Austrian Chamber of Pharmacists

As per December 31, 2009, Austria's 8,3 million inhabitants were supplied by 1.252 public pharmacies (with 23 branches), 46 hospital pharmacies and 950 dispensing doctors (who dispense medicines directly to patients).

In total about 162.000 people are employed in the healthcare sector.

## 1.2 COMPARATIVE HEALTH CARE EXPENDITURES

### HEALTH CARE EXPENDITURE IN PERCENT OF GDP



\* Differences in methodology  
 \*\* 2007 \*\*\* 2006

1995 2008 2009

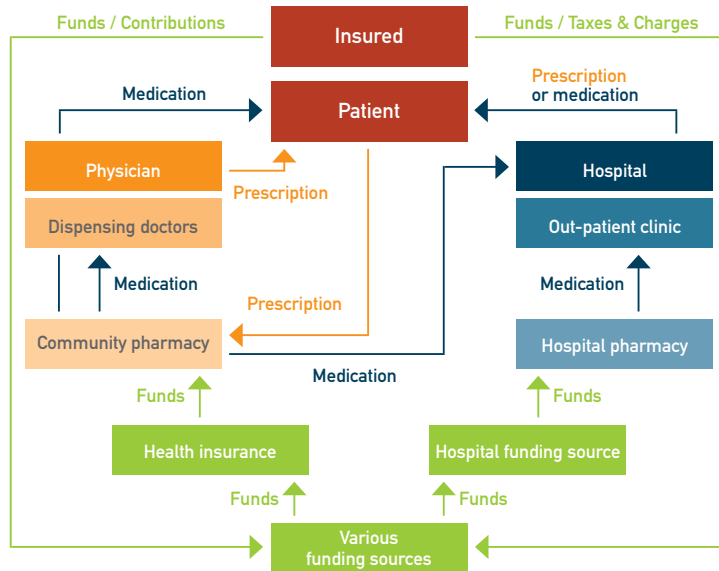
Source: Statistics Austria, OECD

In 2006, Statistics Austria accomplished its calculation scheme for health expenditures in Austria to the "System of Health Accounts", retroactively adjusting values dating back all the way to 1990.

When making a comparison of expenditure on health care at an international level, it should be remembered that SHA has not yet been implemented in all the countries shown (Greece, Ireland and Italy).

## 1.3 STRUCTURE OF THE HEALTH CARE SYSTEM

### STRUCTURE OF AUSTRIA'S HEALTH CARE SYSTEM



Source: PHARMIG

Patients have four different levels of health care providers at their disposal.

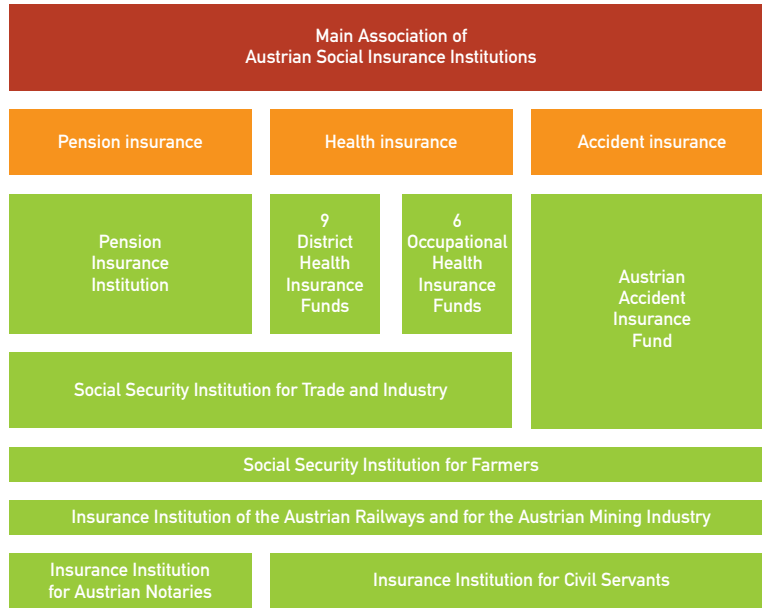
Patients have four different levels of health care providers at their disposal:

- Physicians (general practitioners and specialists), dispensing or non-dispensing
- Hospitals and out-patient wards
- Community pharmacies
- Other medical/therapeutic services

# 1.4

## THE SOCIAL SECURITY SYSTEM

### THE AUSTRIAN SYSTEM OF SOCIAL SECURITY IN 2010



The three pillar system of the Austrian social security system.

Source: HV

The Austrian system of social security covers 99% of the population and rests on three pillars:

- Pension insurance
- Health insurance („health insurance funds“)
- Accident insurance

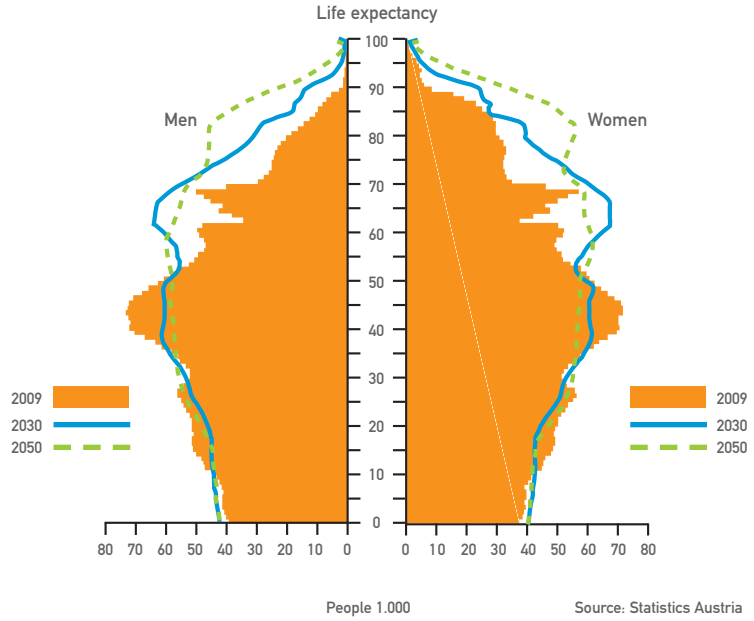
Everyone is compulsorily insured with the respective institution for his/her branch of industry.

The 22 social insurance institutions are coordinated by the Main Association of Austrian Social Insurance Institutions.

# 1.5 POPULATION STRUCTURE IN AUSTRIA

POPULATION PYRAMID 2009, 2030 AND 2050

The life expectancy in Austria has doubled for the last 150 years: women 83 years men 77.4 years



For the year 2009 there live significantly more women than men, which are older than 70. The difference increases with the age.

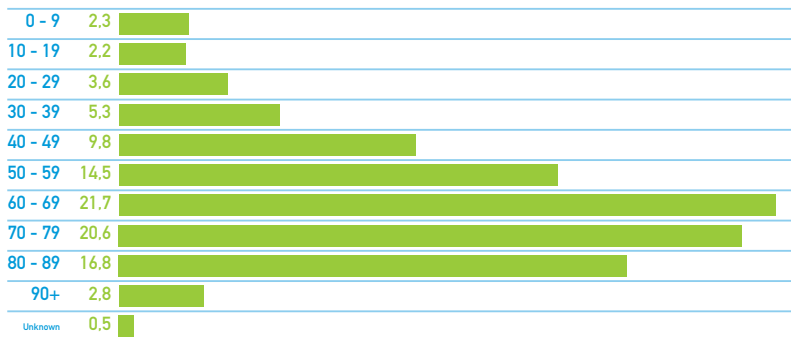


Image: fotolia

# 1.6 DEMOGRAPHIC DEVELOPMENT – AGE AND COSTS

## PHARMACEUTICAL EXPENDITURE FOR PANEL PATIENTS IN 2009

Distribution according to age (by no. of packages) in %

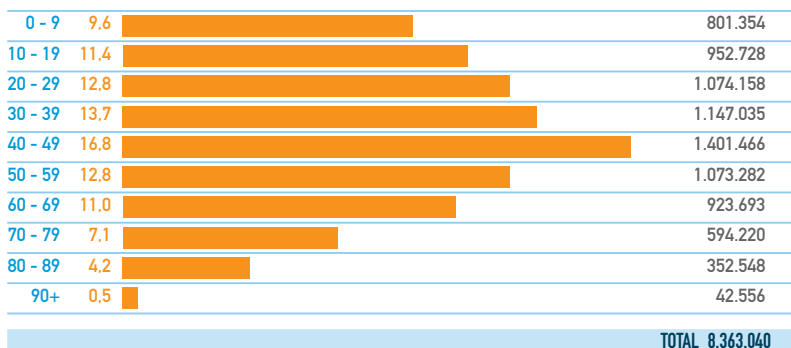


From the age of 60 onwards, the need for pharmaceuticals increases drastically.

Source: Austrian Chamber of Pharmacists

## PERCENTAGE SHARE OF AGE GROUPS IN TOTAL POPULATION 2009

## NUMBER



More than one fifth of the Austrian population is over the age of 60.

Source: Statistics Austria

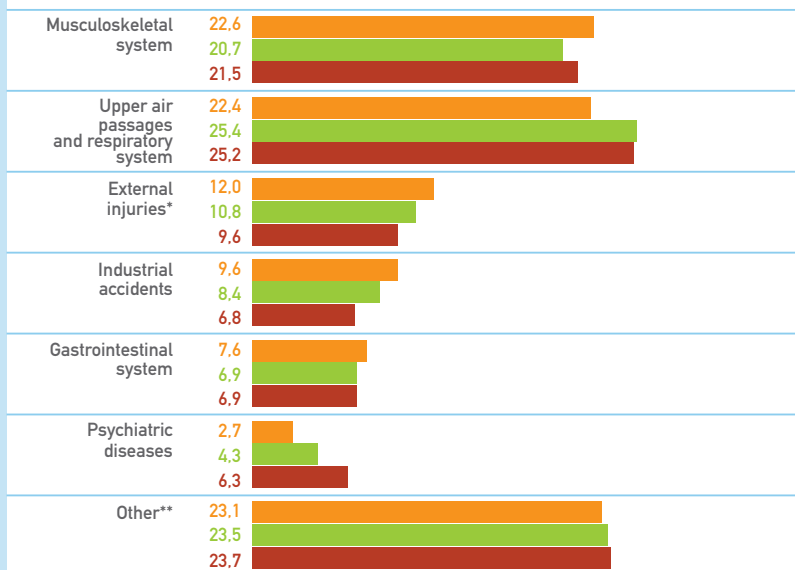
In 2009, persons over the age of 60 made up 22.9% of the Austrian population. Expenditure for medicinal products rises disproportionately in patients over 60 years of age.

## 1.7 FREQUENT CAUSES OF ILLNESS

### ILLNESS GROUPS AS PERCENTAGE OF SICK LEAVE DAYS

Survey group: blue collar and white collar

Diseases of the musculoskeletal system together with the upper air passages and the respiratory system are the main causes for notifications of sickness.



1995 total: 40.280.958 days

2005 total: 35.172.049 days

2009 total: 38.699.956 days

in percent

Source: HV

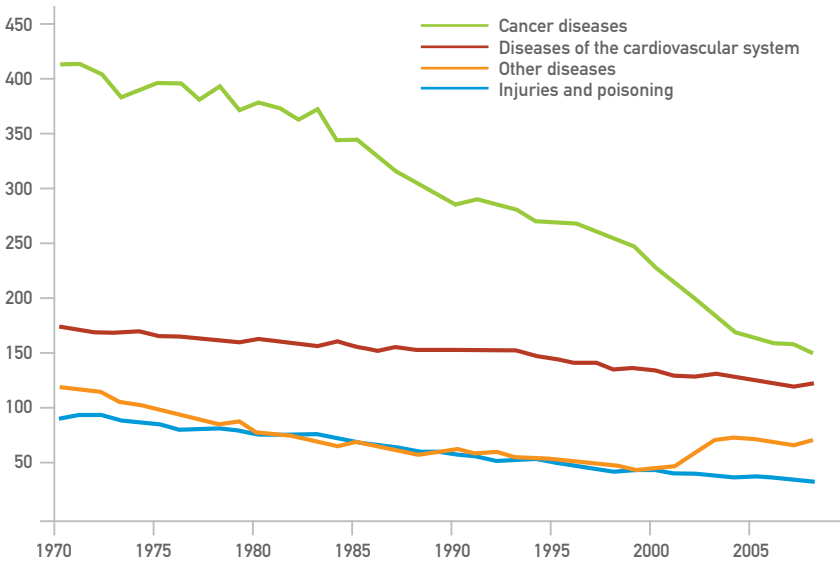
\*e.g. sports injury, road accidents, etc.

\*\*e.g. infections, nervous system, cardiovascular system, etc.

The 3.509.904 cases of illnesses causing absence from work and the 38.699.956 days of employee absence in 2009 show that illnesses of the musculoskeletal system together with diseases of the upper air passages and the respiratory system represent the cause for approximately 47% of the notifications of illness.

# 1.8 MORTALITY

## MORTALITY BY CAUSES OF DEATH



Mortality by causes of death 1970 – 2009, agestandardised mortality rates to 100.000 Persons

Source: Statistik Austria 2009

Since 1970 the mortality of Diseases of the cardiovascular system decreased by 63%, as well as cancer diseases by 45%.

### Classification of ICD 10:

- diseases of the cardiovascular system: heart attack, stroke, hypertension etc.
- malignant neoplasm: cancer diseases (lung, breast, prostata, blood)
- other deseases\*: nutritional and metabolic deseases (Diabetes Mellitus), Virusinfections (AIDS), psychiatric disorders, nervous system etc.

Cardiac diseases, cardiovascular as well as the cancer diseases cause 7 from 10 deaths.

# 2

## PHARMACEUTICAL RESEARCH AND DEVELOPMENT

The greatest motivation for research and development is the quest for new therapies and competition with other pharmaceutical manufacturers.

- In traditional research („screening“), numerous substances (up to 10.000) are tested for their therapeutic suitability in specific indications.
- In other forms of research - genetic engineering, for instance - other, precisely defined therapeutic approaches are tested in advance.

If what we tag a candidate substance is identified, it is further developed on the basis of extensive scientific debate. Once identified, this candidate substance is patented to ensure its economic exploitation. The patented candidate substance then passes through several phases of pre-clinical research. The primary goal of this procedure is to use appropriate methods to test for the substance's potential harm to humans. If necessary, this can also be accomplished through animal testing. Only when the preclinical data indicate that the candidate substance is not toxic (poisonous) for human beings may tests on humans begin.

### Production & Quality Assurance

Pharmaceutical production covers the manufacture of the pharmaceutical form of medicinal products (e.g. tablets, capsules, salves, injections, etc.) as well as the production of active pharmaceutical ingredients and the packaging of the final products plus quality assurance.

The manufacture of medicinal products is regulated by national, European and international legislations. Pharmaceutical manufacturers need an authorization by authority which requires dedicated and sufficient space, technical equipment and facilities for quality control. In the European Union a Qualified Person (QP) has to declare that each batch of a medicinal product has been produced and tested according to the specifications and instructions.

Pharmaceutical production has to be performed in accordance to Good Manufacturing Practice (GMP), which specifies a methodical, hygienic, well documented and controlled manufacture.

GMP defines guidelines for quality assurance of the production processes and surroundings when manufacturing medicinal products and active pharmaceutical ingredients. During pharmaceutical production quality assurance plays a central role, because deviations in quality can have direct influence on the health of the costumers.

Relevant guidelines were compiled for instance by the European Commission, by the Pharmaceutical Inspection Co-Operation Scheme (PIC/S), by the US-American Food and Drug Administration (FDA) as well as globally by the "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use" (ICH). In Austria GMP is implemented into national legislation by the Medicinal Product Site Regulation (german: "Arzneimittelbetriebsordnung", AMBO).

GMP covers amongst others the following areas:

- Duty of care
- Training of staff
- Facilities
- Separation of production, packaging and storage area
- Testing
- Labelling
- Hygiene
- Quality of materials
- Rules for internal and external audits
- In process controls
- Validations
- Quality Control
- Complaints and recall

Monitoring of the regulations is conducted by the health authorities of the respective countries. The AGES PharmMed is the responsible enforcement authority for Austria.

## Clinical Test

Every clinical test must be registered with the Federal Office for Food Safety and be authorised by an ethics committee.

Details regarding the definition of terms, the requirements and the implementation of clinical trials are set forth in the Medicinal Products Act § 2a and § 28 to § 48.

The relevant information for the marketing authorisation of a medicinal product is collected in phases I and IIIa of the clinical study. Further testing conducted after submission of an application for marketing authorisation or after the authorisation has been awarded (e.g. long-term studies of influencing factors of the course of illnesses or detailed investigations on pharmacokinetics with renal or hepatic insufficiency patients) is implemented in the so-called phase IIIb or phase IV studies.

### **PHASE I: TESTING OF PHARMACOKINETICS**

In phase I, the medicinal product is administered for the first time in order to determine its behaviour in a healthy person. Objective: information regarding tolerability, resorption, elimination and any metabolites. Phase I testing is conducted with a small number (10 to 50) of healthy volunteers. Healthy test subjects are preferred because the manner in which the tested substance reacts should not be distorted by pathological conditions. If the active agent is expected also to have toxic properties (as is the case with substances used for oncological disorders), respectively within the development of special indications (e.g. HIV) only patients with the respective disease are included in phase I of the study.

### **PHASE II: ASCERTAINING THE DOSAGE**

In the next stage, the controlled phase II test, the substance's pharmacodynamic effect is explored. Objective: to ascertain the therapeutic dosage and obtain a biological signal proving the effectiveness of the substance. Moreover, the aim is to obtain information regarding tolerability and any interactions.

In this phase, the group of test patients with the relevant illness consists of 50 to 200 patients. The studies are generally controlled, i.e. they include a control group and are double-blind studies (neither physician nor patient know, whether the active agent is administered).

### PHASE III: ESTABLISHING THE THERAPEUTIC EFFECTIVENESS

Unlike the previous phases, the test in phase III is carried out on a large group of patients (with the relevant illness). The size of the patient group is determined depending on the indication in order to ensure reliable proof of the effectiveness and to detect any rarely occurring side effects. The duration of treatment of the individual patients in the course of the clinical study depends on the illness; in the case of chronically progressing disorders, the treatment may even last several years.

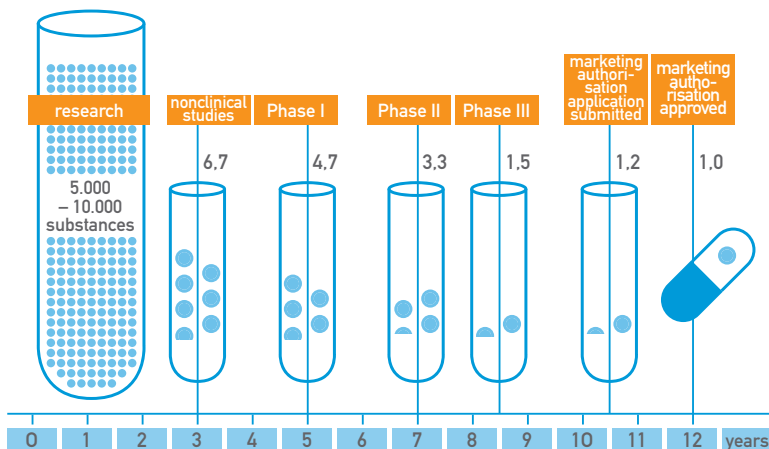
As a rule, these multi-centre studies are conducted in several countries at the same time (multinational) in order to keep the duration of the overall study as short as possible. The phase III studies are controlled and double-blind in nature just like the studies in phase II in order to ensure that neither the physician nor the patient know whether the new active agent or the control substance were administered. This makes sure that any effect on the treatment result is reduced to a minimum.

Once phase III of the clinical study has been positively concluded, an application can be submitted to the appropriate authorities for authorisation of the medicine.

### PHASE IV: CLINICAL STUDY AFTER AUTHORISATION

In this phase, conducted in the form of a clinical trial, further data is examined to verify whether it complies with the requirements of the authorisation. The studies in phase IV are subject to the same conditions as the clinical studies in phases I through III.

### DEVELOPMENT PHASES OF A MEDICATION



Data = Number of Substances/ Phase: absolute Number

Source: VFA e. V.

### Non-interventional study (NIS)

A NIS (e.g. Case-control study, Cross-sectional study, Observational study, Analysis of administrative registers) is the systematic examination of an authorised medicinal product administered to patients. The type and duration of the administration correspond to the approved summary of product characteristics and patient information leaflet. No additional diagnostic, therapeutic or strainful measures may be taken. A comparison with other medicinal specialties is also admissible within the scope of customary medicinal practice. NIS can be used to provide proof of the effectiveness of medicinal products under practical conditions and to document side effects, which are not recorded in the course of the clinical study programme due to the restriction in the number of patients included.

With 1st of September 2010 the regulation of implementation of NIS entered into force. The regulation provides that any non interventional study before the implementation has to be reported to BASG. The NIS register is located at AGES PharmMed.

### Development costs

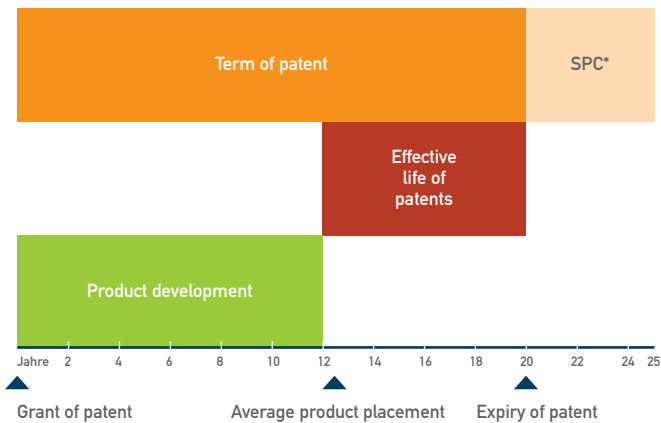
According to recent studies, the average cost of developing a new medicinal product is up to Euro 1,5 billion. The reasons for these enormously high costs are the substantially increased documentation and safety requirements for clinical trials, on the one hand, and the need for a greater number of patient volunteers, on the other.

### Research location Austria

As the trend of recent years shows, Austria is becoming an increasingly attractive research location. In particular for biotech start-ups, Austria is a very popular location. Since 2008, there is also Europe's first „Research Center Pharmaceutical Engineering“ (RCPE) located in Graz, whose aim is to optimise product and process development in the pharmaceutical industry.

## 2.1 DURATION OF PATENT PROTECTION

### DURATION OF PATENT PROTECTION



\* supplementary protection certificate max. 5 years

Source: PHARMIG

Patents for medicinal products are effectively used for less than 8 years.

Innovative medicinal products (as all other goods) are protected for 20 years under patent law. However, medicinal products must be patented as the intellectual property of the inventor at a comparatively early stage of their development.

From the time a medicinal product is patented until it becomes available to patients, an average of 12 years elapses. This period is necessary for pre-clinical testing and the official marketing authorisation process (see Chapter 3). Thus, on average, the actual effective life of a patent is less than 8 years.

To extend the patent term, the patent holder (marketing authorisation holder) can apply for additional protection (Supplementary Protection Certificate, SPC) of his invention. The SPC grants an extension of the patent period for up to five years.

### DATA EXCLUSIVITY

Irrespective of the patent protection, what is known as data exclusivity (data protection) has been uniformly provided for across the EU and has been applicable for all marketing authorisation applications since October 30, 2005. Data exclusivity specifies as of when a reference to the documents of an original product is allowed in an application for generics. Generally, this is not permissible until 8 years after the first-time authorisation in the EU. After expiry of another 2 years (i.e. after 10 years in total), the generic medicinal product may be placed on the market for the first time ("8+2 rule").

When the marketing authorisation holder of an original product successfully applies for new fields of application within the first 8 years after the first authorisation was awarded, data exclusivity is extended from 10 to 11 years ("8+2+1 rule").

### PARTICULARITIES IN PATENT PROTECTION AND DATA EXCLUSIVITY

There are several particularities applicable for patent protection and data exclusivity in the EU, which promote the generic industry on the one hand while creating incentives for innovative research in the field of medicinal products on the other.

- **ROCHE-BOLAR RULE:** In the EU, studies and investigatory work for patent-protected medicinal products may – for the preparation of documents for generics applications for marketing authorisation – be conducted prior to the expiry of the patent protection already.
- **PEDIATRIC MEDICINAL PRODUCTS:** Since January 2007, the suitability for children of all new medicinal products in the EU must be verified. New, patent-protected medicinal products which are suitable for administration to children (paediatric medicinal products), may assert an additional 6 months of patent protection. Any medicinal products whose patent protection has already expired, may apply for an additional year of data exclusivity – upon submission of new paediatric data within the first 8 years of data exclusivity.
- **ORPHAN DRUGS:** An orphan drug status may be applied for medicinal products for rare diseases from EMA (European Medicines Agency). Under specific circumstances, orphan drugs enjoy market exclusivity once they have been authorised. This means that the EMA or a national authority may not accept any further application for marketing authorisation in this indication or issue an authorisation in this indication once a first-time marketing authorisation of an orphan drug has been awarded. In specific cases, this market exclusivity is reduced to 6 years.

## 2.2 A EUROPEAN COMPARISON OF R&D INVESTMENTS

### RESEARCHRATE: RATIO OF INVESTMENT IN R&D/SALES

Pharmaceuticals & Biotechnology	15.9%	<div style="width: 15.9%;"></div>
Software & Computer Systems	9.9%	<div style="width: 9.9%;"></div>
Technology Hardware & Equipment	8.7%	<div style="width: 8.7%;"></div>
Health Care Equipment & Services	6.5%	<div style="width: 6.5%;"></div>
Leisure Goods	6.2%	<div style="width: 6.2%;"></div>
Automobiles & Parts	4.7%	<div style="width: 4.7%;"></div>
Electronic & Eletronical Equipment	4.4%	<div style="width: 4.4%;"></div>
Aerospace & Defence	3.9%	<div style="width: 3.9%;"></div>
Chemicals	3.4%	<div style="width: 3.4%;"></div>
Industrial Engineering	3.1%	<div style="width: 3.1%;"></div>
All Sectors	3.5%	<div style="width: 3.5%;"></div>

in percent

Quelle: The 2010 EU Industrial R&D Investment Scoreboard

The Pharmaceutical- & Biotechnology industrial sector is still the most leading branch in the area R & D for the EU: 15,9 % of Sales are invested in R & D, which is significantly more than in other sectors (EU average of 3,5%)



## 2.3 MEDICINAL PRODUCT INNOVATION

### TIMELINE OF PHARMACEUTICAL DEVELOPMENT

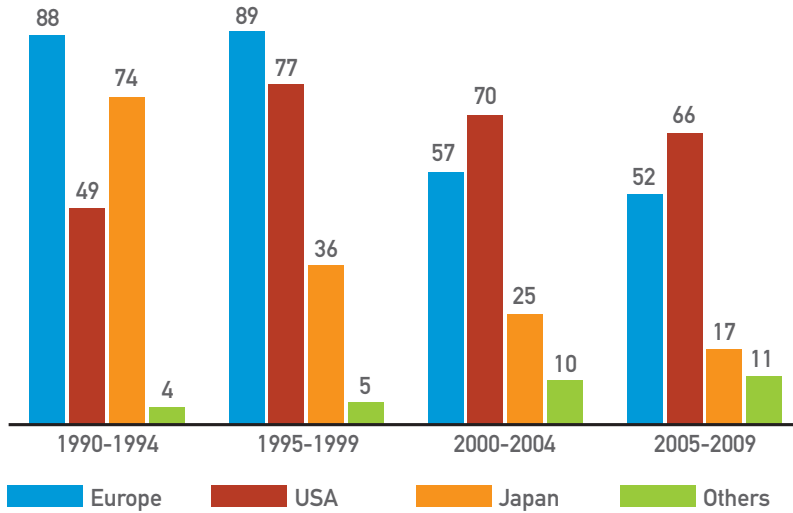
1848	Chloroform used as an anaesthetic in surgery
1891	First drug against diphtheria, an infection of the respiratory tract that is usually lethal with children: diphtheria antiserum
1899	Acetylsalicylic acid: analgesic, antipyretic and anti-inflammatory
1910	First antibacterial preparation: salvarsan against syphilis
1922	Insulin used to treat diabetes
1927	Active vaccine against tetanus
1939	First anticoagulant used to prevent thrombosis
1944	Penicillin available as drug
1948	First strong anti-inflammatory: nature-identical cortisone
1956	First antidepressant (iproniazid)
1957/58	First cytostatic against leukaemia (chlorambucil) and lung cancer (cyclophosphamide)
1960	First immunosuppressant, azathioprine, made organ transplants possible
1960	First „pill“ for contraception
1963	First vaccine against measles
1964	Betablocker against heart disease
1968	Faktor VIII concentrates to treat blood disorders (from donor blood)
1976	First inflammation-reducing asthma drug (derived from cortisone)
1980	Successful eradication of smallpox through vaccination
1980	First ACE inhibitor for the reduction of blood pressure
1982	First genetically engineered medicinal product in the German and US market: human insulin
1983	First (anti-)hormone therapeutic agent against the reoccurrence of breast cancer
1983	First calcineurin inhibitor doubles the functional life of kidney transplants
1987	First preparation against HIV / AIDS
1987	Statins used to lower cholesterol and prevent cardiovascular disease
1991	New drug that considerably reduces nausea during chemotherapy in cancer treatment
1993	First drug that slows down specific forms of multiple sclerosis (MS)
1996	First three-drug combination to delay the outbreak of AIDS in patients infected with HIV for years
1998	First oral drug for the treatment of erectile dysfunction
1999	Cure for hepatitis C based on a combination of drugs (an alpha interferon + a synthetic virustatic)
2000	First antibody therapy against breast cancer metastasis
2001	First specific drug against chronic myelotic leukaemia
2004	First anti-body preparation against intestinal cancer
2005	First drug to cut off tumour blood supply
2006	First vaccine against cervical cancer
2006	First drug for the treatment of morbus pompe, a rare hereditary disease
2007	First drug against liver cancer
2007	Drugs with dual mechanism of action against HIV infection
2009	First trifunctional antibody; for the treatment of ascites in patients with EpCAM-positive tumours

Source: VFA

(All the information provided refers to the year in which the medicinal product was first marketed internationally.)

## 2.4 NEW MOLECULAR ENTITIES

### NEW MOLECULAR ENTITIES SINCE 1990



Angaben in Absolut

Source: SCRIP/EFPIA, 2010

146 new substances (chemical and biological) were introduced on the global market in the years 2005-2009. 52 of these substances were developed in Europe.



Image: fotolia

# 3

## MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS

### 3.1 PROCEDURES AND REQUIREMENTS

There are three different procedures for the authorisation of medication.

Medicinal products may only be put into circulation by the marketing authorisation holder (MAH) after they have been officially “approved” by the authorities. The legal basis for this approval in Austria is the frequently amended law of 1984 relating to the manufacture and distribution of medicines (MPA, Medicinal Products Act).

The authorisation is granted if the applicant can demonstrate that the expected benefits of a medicine exceed the expected side effects. The proof is provided by submitting pharmaceutical, preclinical data as well as clinical data.

There are three different procedures to obtain a marketing authorisation:

#### ■ NATIONAL PROCEDURE

The (purely) national authorisation procedure is set forth by the Medicinal Products Act and is only applicable for medicinal products which are to be authorised for Austria. AGES PharmMed evaluates the application while the Federal Agency for Safety in Health Care award the marketing authorisation.

#### ■ MUTUAL RECOGNITION (MRP)/DECENTRALISED PROCEDURE (DCP)

The authorisation procedure is applicable when the medication is to be approved in more than one EU country. This procedure is based on the principle of mutual recognition of marketing authorisations from the Member States. The mutual recognition procedure should be applied for an authorisation already existing in one of the Member States. The decentralised procedure is only applicable when there is no other corresponding authorisation in one of the Member States. The applicant is free to choose in which Member State the medicinal product is to be approved. A basic prerequisite is the positive approval of the authorisation application by all Member States involved in the process. Every Member State shall issue a national marketing authorisation once the procedure has been completed.

#### ■ CENTRALISED PROCEDURE (EU)

Authorisation through this procedure is mandatory for biotechnical medicinal products, medicinal products for novel therapies, certain veterinary drugs, orphan drugs as well as new substances for the following therapeutical indications:

- acquired immunity deficiency syndrome
- cancer
- neurodegenerative diseases
- diabetes
- immune mediated disease and other immune diseases
- viral diseases

In this procedure, the evaluation is conducted not by the national authority but by the European Medicines Agency (EMA) headquartered in London. Based on the EMA evaluation, the EU Commission awards an EU authorisation for all Member States.

#### REQUIREMENTS FOR THE MARKETING AUTHORISATION:

In the case of innovative products or original preparations, the applicant for authorisation must submit to the authority a complete dossier (documents and study results for pre-clinical and clinical as well as medicinal product data).

For generic medicinal products (me-too products to be placed on the market after the expiry of the patent or after expiry of data exclusivity of the original preparation), the applicant for authorisation must submit only a portion of the pharmaceutical data – applicants for generics are therefore exempted from a large part of the requirements to be met by an original preparation in the authorisation procedure. Instead, the applicant for a generic medicinal product has recourse to the available data of the original preparation. One therefore speaks of a “referring authorisation”. This exemption markedly decreases the term of the marketing authorisation.

#### IN THE APPROVAL PROCEDURE, THE FOLLOWING IS ALSO ESTABLISHED:

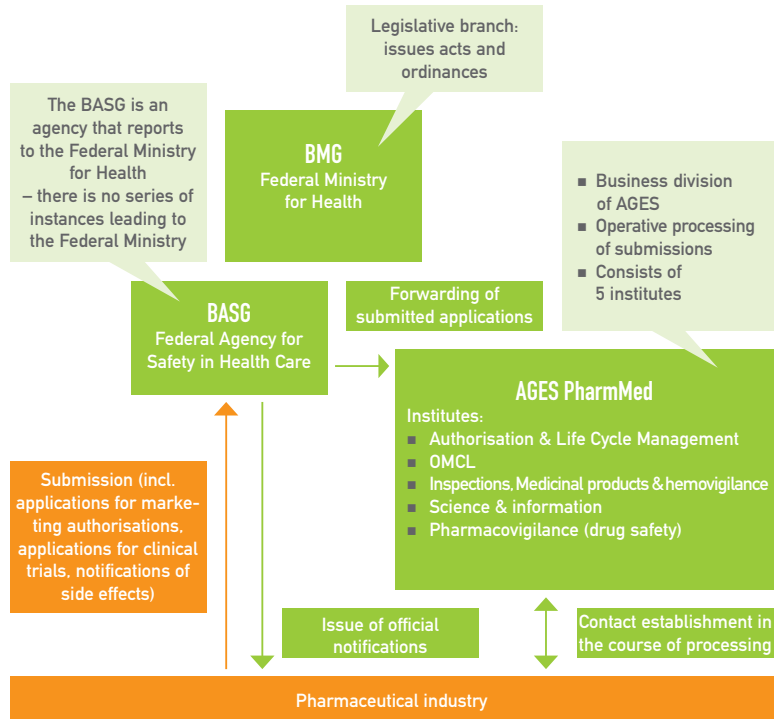
- Compulsory wording of the summary of product characteristics (for physicians, pharmacists and other specialists)
- Compulsory wording of the patient information leaflet (for patients and other laymen)
- Tagging (labelling of the outer packaging)
- Prescription status (information on whether the medication requires a prescription or not; see section 3.3)
- Distribution channel (e.g. to be sold only at pharmacies, required refrigerated transport, etc.)

When a pharmaceutical is approved according to the MPA, it is designated as a medicinal product.

## COMPETENT AUTHORITIES IN AUSTRIA

Until the end of 2005, marketing authorisations for medicinal products were granted by the Federal Ministry for Health – starting in January 2006, the Federal Agency for Safety in Health Care (BASG) took on this sovereign responsibility. The operative performance of the pharmaceutical and medicinal product system (incl. authorisation, pharmacovigilance, blood safety, inspection system, clinical test) was also shifted from the responsibility of the Federal Ministry for Health to AGES PharmMed. The legal basis for this extensive reorganisation is the Health and Food Safety Act (GESG – Federal Law Gazette I 139/2006).

AGES PharmMed ist one of the 7 business divisions of AGES (Agency for Health and Food Safety) – a private services company owned by the Ministry of Health and the Ministry of Agriculture. The Federal Agency for Safety in Health Care was set up to support AGES PharmMed. The Federal Agency for Safety in Health Care (BASG) is a federal agency responsible for the implementation of state-conferred responsibility (e.g. issue of notification). The operational level is represented by AGES PharmMed with its 5 institutes (status: 2010).



## 3.2 NUMBER OF MEDICINAL PRODUCTS

### TOTAL NUMBER OF APPROVED MEDICINAL PRODUCTS FOR HUMAN USE 2009

Medicinal Products for human use, total	12.330
Centralised Authorisation Procedure (EMA)	576
Approval according to § 9a* MPA (full application) and § 10* MPA (generic application)	7.771
Simplified procedures (§ 9e*, § 9c* MPA)	101
Simplified approval according to § 17a MPA Federal Law Gazette. I no. 35/2004	776
Alleviated authorisation for desensitization products (§ 7a MPA)	53
Biogenic medicinal products	122
Homeopathic medicinal products	967
Pharmacy-proprietary medicinal products	1.927
Radioactive medicinal products	37

Source: AGES PharmMed (as per 12.01.2010), European Commission (as per 12.04.2011)

Marketing authorisations acc. to § 17a MPA Federal Law Gazette I no. 35/2004 (MPA of 2005) pertain to medicinal products which consists solely of known and prescription-free medicinal products and have been granted by virtue of a “simplified” procedure. With the enactment of the MPA 2006 (January 2, 2006), this procedure was abolished. Medicinal products authorised pursuant to the old § 17a procedure (MPA before 2006) may still be submitted until April 30, 2011.

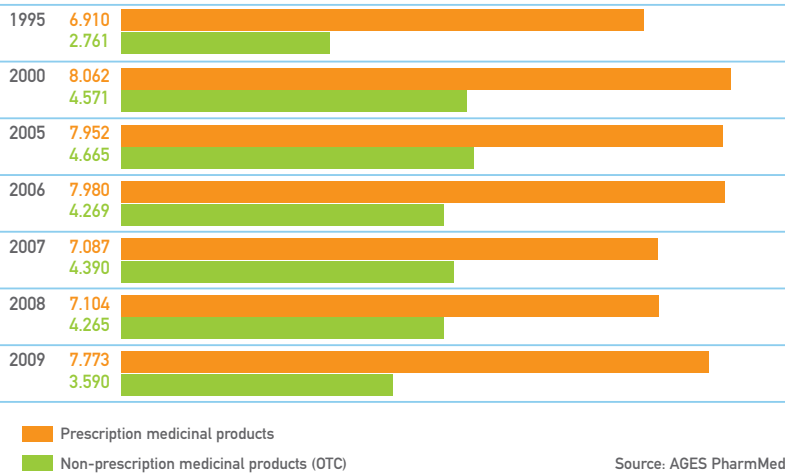
Pharmacy-proprietary medicinal products are manufactured by pharmacies directly; they are approved as non-prescription specialities of a specific pharmacy and may be sold only by the respective pharmacy. Due to a MPA amendment approved pharmacy-proprietary medicinal products have been transferred to the status of registered pharmacy-proprietary medicinal products since September 2009.

\*the stated §§ refer to the MPA of 2006

### 3.3 PRESCRIPTION AND NON-PRESCRIPTION MEDICINAL PRODUCTS

#### STATUS OF PRESCRIPTION MEDICINAL PRODUCTS (MEDICINAL PRODUCTS FOR HUMAN USE EXCLUSIVE OF HOMEOPATHIC MEDICINES)

Approximately 68% of approvals are prescription medicinal products.

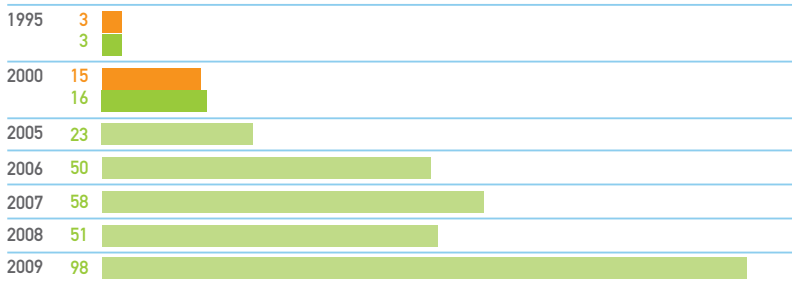


Around 32% of the medicinal products for human use approved in Austria (without homeopathic medicines) are available as non-prescription medicinal products in pharmacies.

The prescription status of the medicinal products is determined during the authorisation procedure. The Prescription Act together with the Austria's Prescription Ordinance (Rezeptpflichtverordnung) are the legal basis for this decision.

## 3.4 INNOVATIVE AND GENETICALLY ENGINEERED MEDICINAL PRODUCTS

### CENTRALISED PROCEDURE FOR MEDICINAL PRODUCTS IN THE EU



until November 2005:

Procedure A: compulsory Centralised Procedure

(genetically engineered and bioengineered medicinal products)

Procedure B: voluntary Centralised Procedure (innovative substances)

as of November 2005:

Centralised Procedure as of 2005

Source: European Commission (2009: as per 11.04.2011)

A centralised procedure has been in place since 1995, at the completion of which a European Authorisation is awarded (see section 3.1). In a centralised procedure, the authorisation is granted by the EU Commission and is valid in all EU Member States.

Until November 2005, a difference was made between the compulsory centralised procedure (for all genetically engineered and biotechnical medicinal products) and the voluntary centralised procedure (for innovative substances). In the voluntary centralised procedure, the applicant was able to choose between the centralised and the mutual recognition procedure.

Since the new EU directive concerning the centralised procedure has taken effect in November 2005, only one compulsory centralised procedure remains applicable for certain medicinal products (see page 25).



Bild: fotolia

The Genetic Engineering Act prohibits any tampering with the germline.

### GENETIC ENGINEERING IN MEDICINE

The directive for the patent protection of biotechnical inventions, which was approved by the European Parliament in early 1998, provides legal security for all stakeholders, ensures therapeutic progress for patients and supports the competitiveness of Europe vis-à-vis the USA and Japan.

The crucial evaluation of biotechnology's ethical aspects is ensured by the so-called "European Group for the Ethics of Science and New Technologies" of the European Ethics Committee.

The Austrian Genetic Engineering Act generally prohibits any tampering with the germline. It permits gene analyses, provided these are carried out with the consent of those involved and after consultation with a physician. A somatic gene therapy for the treatment of hereditary diseases is also permitted under certain circumstances.

# THE PHARMACEUTICAL SUPPLY SYSTEM

# 4

## 4.1 PHARMACEUTICAL PRODUCTION IN EUROPE

### PHARMACEUTICAL PRODUCTION IN SELECTED EUROPEAN COUNTRIES 2008

	Euro million	Euro per inhabitant	estimated population mid-2008
France***	34.600	558	62.036.000
Germany	27.105	329	82.264.000
Italy***	22.984	386	59.604.000
Great Britain**	22.857	373	61.231.000
Switzerland***	22.841	3.029	7.541.000
Ireland**	17.540	3.953	4.437.000
Spain***	14.108	317	44.486.000
Sweden***	6.372	692	9.205.000
Netherlands*	5.664	343	16.528.000
Denmark***	5.551	1.017	5.458.000
Belgium***	5.518	521	10.590.000
Austria	2.082	250	8.337.000
Portugal***	2.054	192	10.677.000
Finland	987	186	5.304.000
Greece	825	74	11.137.000
Norway**	679	142	4.767.000

\*\*\*Estimates (GR: provisional data) \*\*2007 \*2005

Source: EFPIA, Statistics Austria

France is the leader in pharmaceutical production.

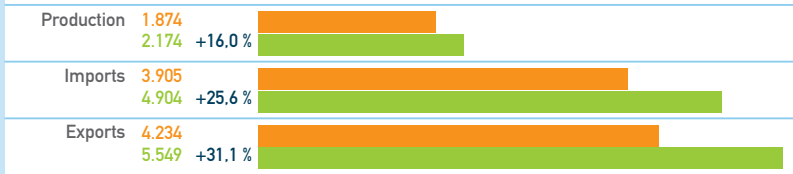
In 2008, France, Britain, Germany and Italy produced the majority of pharmaceuticals.

Ireland and Switzerland reported the highest production value per capita. Austria, with 250,- Euro per capita, is far below the mean value of 773,- Euro per capita of the selected European countries.

## 4.2 PHARMACEUTICAL PRODUCTION IN AUSTRIA

### PHARMACEUTICAL PRODUCTION IN AUSTRIA. IMPORTS AND EXPORTS

Both production and imports and exports of pharmaceuticals are steadily rising.



2006

2009

in Euro million

Source: Statistics Austria

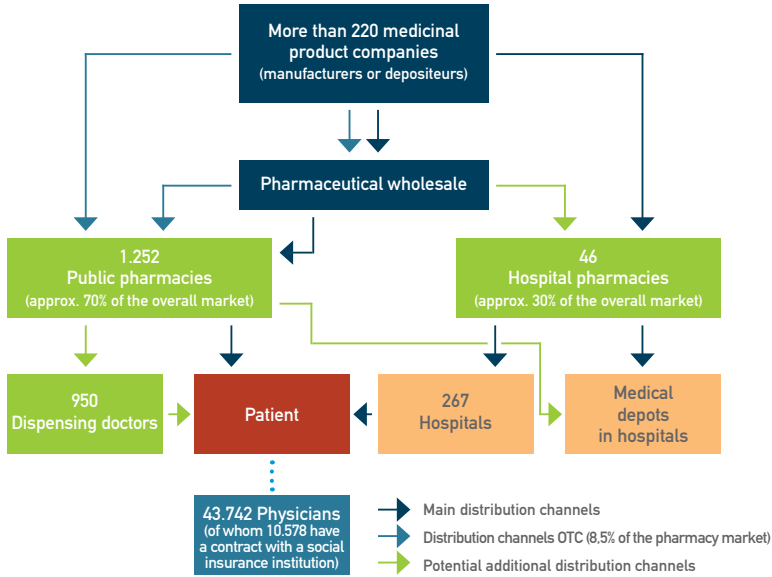
In 2009, the value of medicinal product imports exceeded exports by some 13,2%.



Image: istock

# 4.3 PHARMACEUTICAL DISTRIBUTION

## THE AUSTRIAN MEDICINAL PRODUCT DISTRIBUTION SYSTEM 2009

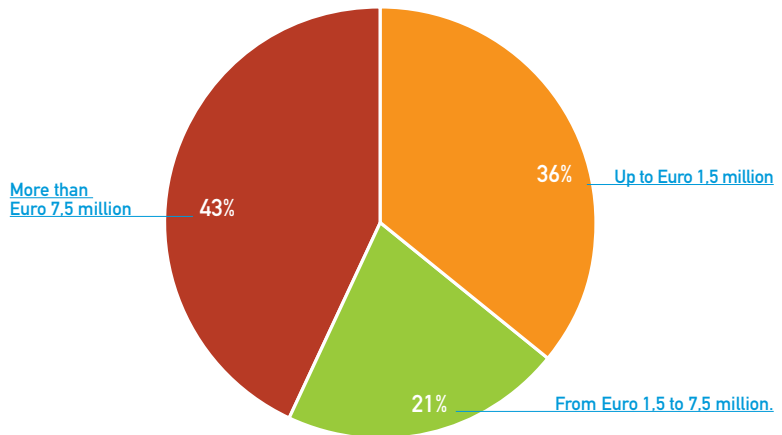


Source: PHARMIG, Statistics Austria, IMS, HV, BMG

About one third of the medicinal products were sold to hospitals, and two thirds to public pharmacies, i.e. the out-patient sector (based on value).

## 4.4 THE SIZE OF PHARMACEUTICAL COMPANIES IN AUSTRIA

SIZE OF PHARMACEUTICAL COMPANIES 2010



Source: PHARMIG

according to yearly sales of Pharmig members in percent

The business volume of the Austrian pharmaceutical companies that either produce medicinal products themselves (manufacturers) or import finished medicinal products (distributors) to Austria varies greatly.

# THE AUSTRIAN PHARMA- CEUTICAL MARKET

# 5

## DATA FOR INDIVIDUAL MARKET SEGMENTS

In 2009, the Austrian medicinal product market reported sales of 2,99 billion euros and a sales volume of 232.7 million packages. This represents a growth rate of 2,6% in value and 2,3% in volume. All sales data given are based on wholesale purchasing price.

From the perspective of the manufacturers and distributors, in regard to sales the medicinal product market is divided into two segments:

- Hospital market (intramural sector) Euro 923,2 million
- Public pharmacies and dispensing doctors (extramural sector) Euro 2.072,7 million

Source: IMS

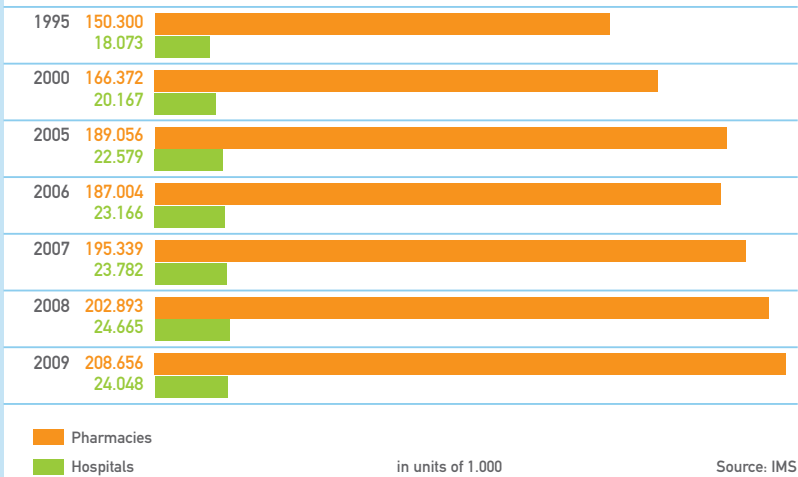


Image: fotolia

## 5.1 QUANTITY AS A MARKET FACTOR

### SOLD PACKAGES

In 2009, the number of sold packages grew by 2.3%.

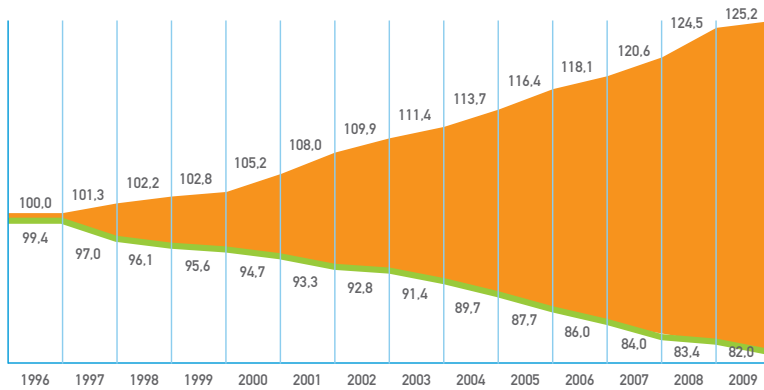


In 2009, 232.7 million packages were sold in Austria. Around 10% of these went to hospitals (hospital pharmacies) and around 90% to pharmacies in the extramural sector.

## 5.2 PRICE AS A MARKET FACTOR

### 5.2.1 PRICE TRENDS

PRICE TRENDS (BASED ON WHOLESALE PURCHASING PRICE)



■ Consumer price index (annual average), CPI 96 (1996=100)  
■ Pharmaceutical price index (based on ex factory prices)

in percent

Source: Statistics Austria, IMS

Prices for medicinal products already on the Austrian market have decreased annually since 1995: The price for a fictitious package of medicine costing 10 Euro in 1995 is only 8,2 Euro in 2009.

The CPI (consumer price index), however, underwent the exact opposite development.

The divergence between consumer price index and pharmaceutical price index continues year to year.

## 5.2.2 PRICES OF MEDICINES

### PRICES APPLICABLE TO MEDICINES

- **Price ex works (PeW/DAP):** :  
Manufacturer/Depositeur -> Wholesale
  - **Pharmacy purchase price (PPP):**  
Wholesale -> Pharmacy
- if reimbursed:
- **Reimbursement price:**  
Pharmacy -> health insurance
- if a private purchase:
- **Pharmacy selling price:**  
Pharmacy -> Customer

### Price-example:

€ 100,-
€ 108,50 = PeW + Wholesale charge*
€ 122,95 = PPP + Pharmacy charge* – Prescriptionfee** (Price exkl. VAT.***)
€ 177,05 = PPP + Pharmacy charge* + 15% privatesale charge* (inkl. VAT)**)

\*\* Prescriptionfee since 1.1.2011: € 5,10,-; \*\*\* VAT. since 1.1.2009: 10%

Source: PHARMIG

All prices and margins in the pharmaceutical distribution chain are subject to public control by authorities/social insurance.

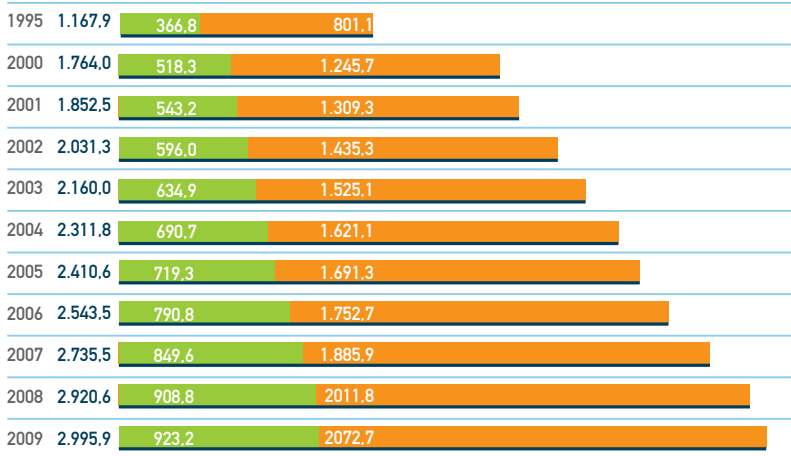
- Price ex works: this is a price that a wholesaler pays for a medicine (excl. VAT)
- Pharmacy purchase price: this is a price which a pharmacy pays for a medicine, (excl. VAT)
- Pharmacy selling price: this is a price which a costumor pays for a medicine
- Reimbursement price: this is a price which a health insurance pays for medicines, that are reimbursable; the prescription fee for 2011 (since the 1st of January) amounts to € 5,10 per Pack.



Image: fotolia

## 5.3 PHARMACEUTICAL SALES

### PHARMACEUTICAL SALES (BASED ON WHOLESALE PURCHASING PRICE)



■ Hospitals  
■ Pharmacies

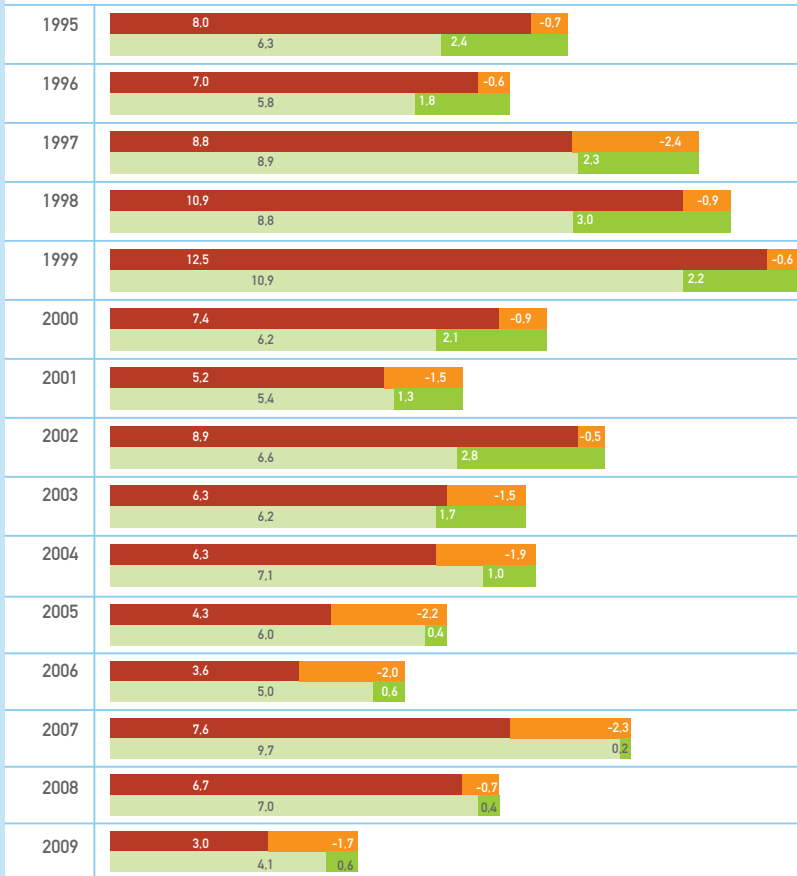
in Euro million

Source: IMS

Structural changes in pharmacotherapy were once again the strongest drivers of sales growth in 2009. Pure increases in quantity are also covered in this category, including increases in demand due to demographic changes (see section 5.4).

# 5.4 ELEMENTS OF GROWTH

ELEMENTS OF GROWTH (BASED ON WHOLESALE PURCHASING PRICE)



■ Total growth     ■ Structural effects  
■ Price change     ■ New launches     in percent

Source: IMS

The growth of the medicinal product market is influenced by a number of factors.

### **CHANGE IN PRICE**

Price changes are changes in the price of a certain product already introduced in the market. Changes in average prices due to new product launches are not covered under this category. The development of medicinal product prices has been an impediment to growth since 1994 (see section 5.2.1).

### **NEW PRODUCT LAUNCHES**

New launches cover new products, provided that they contain new active agents, in the year of the product placement and in the subsequent year. They replace previous forms of therapy or make pharmacotherapy possible for the first time. After the second year following the product launch, the market changes of these products are taken into account under the category structural changes.

### **STRUCTURAL EFFECTS**

We have summarised the following factors:

#### **STRUCTURAL CHANGE**

Structural changes include all types of substitution of medicinal products, unless they are covered in the category New Product Launches, attributable to changes in prescribing habits, replacement of previous forms of therapy, etc. Pure increases in quantity are also covered in this category, including increases in demand due to demographic changes.

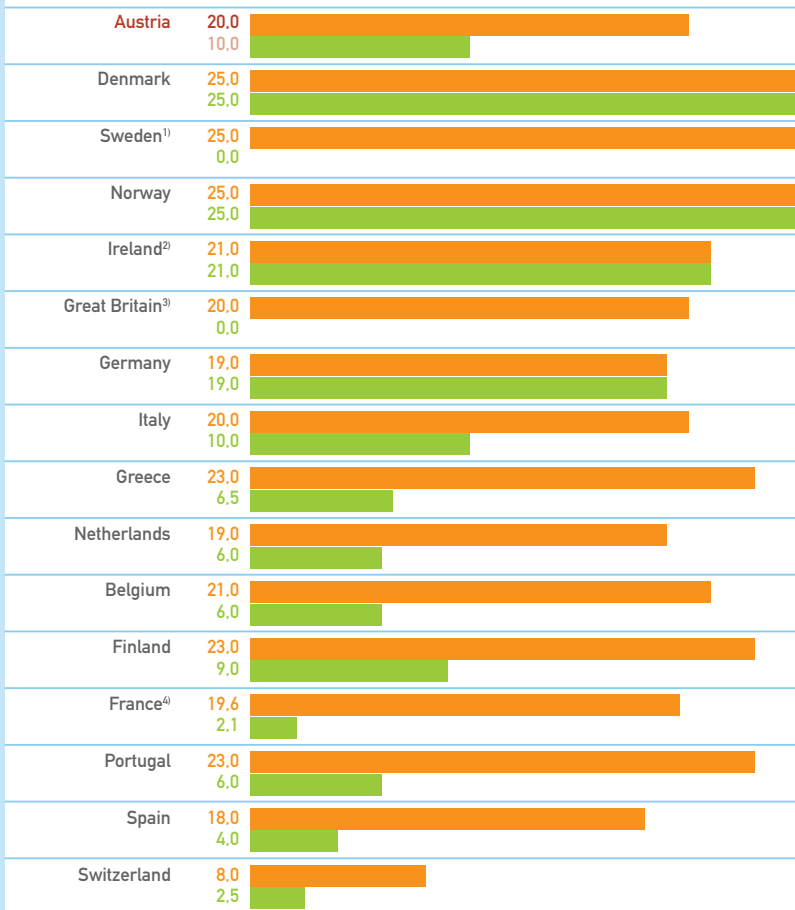
#### **EXPANDING THE RANGE OF PRODUCTS**

This growth factor includes all extensions of the product range in terms of quantity (product differentiation) of the medicinal products already available on the market for more than two years, e.g. introduction of new pack sizes or forms of administration, etc.

## 5.5 VALUE-ADDED TAX AS A MARKET FACTOR

In the EU, a wide range of sales tax rates are still applicable for medicinal products, from 0% to 25% (Scandinavian countries).

### VALUE-ADDED TAX (VAT) IN EUROPE PER 1.1.2011



Normal rate    Rate for medicinal products    in percent

Source: European Commission

1) Sweden: 0% on prescription. 25% for OTC

2) Ireland: 0% for oral form of administration, 21% for all other medicinal products

3) Great Britain: 20% for medicinal products purchased by hospitals and OTC preparations. 0% on prescription

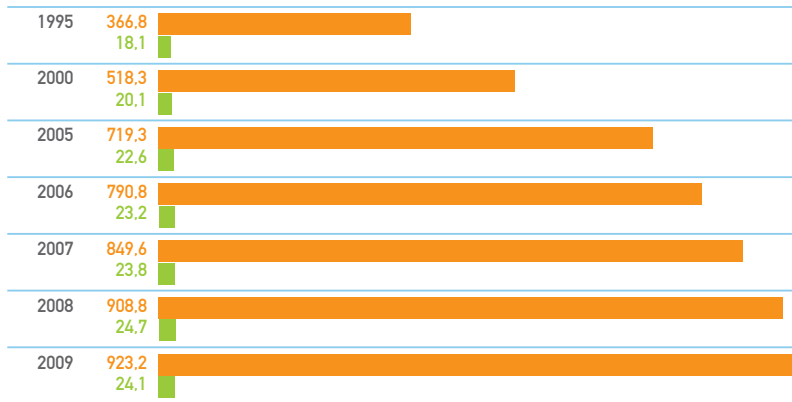
4) France: 2.1% for medicinal products reimbursed by the health insurance. 5.5% for all others

Since January 1, 2009, a reduced VAT rate of 10% applies to pharmaceuticals in Austria.

# 5.6 KEY MARKET SEGMENTS

## 5.6.1 THE HOSPITAL

### HOSPITAL TURNOVER (BASED ON WHOLESALE PURCHASING PRICE)



■ Turnover in Euro millions  
■ Packages in millions

Source: IMS

Hospital sales represent approx. 30% of the total market.

In the year 2009, the hospital segment increased by 1,6% in sales and decreased by 2,5%.

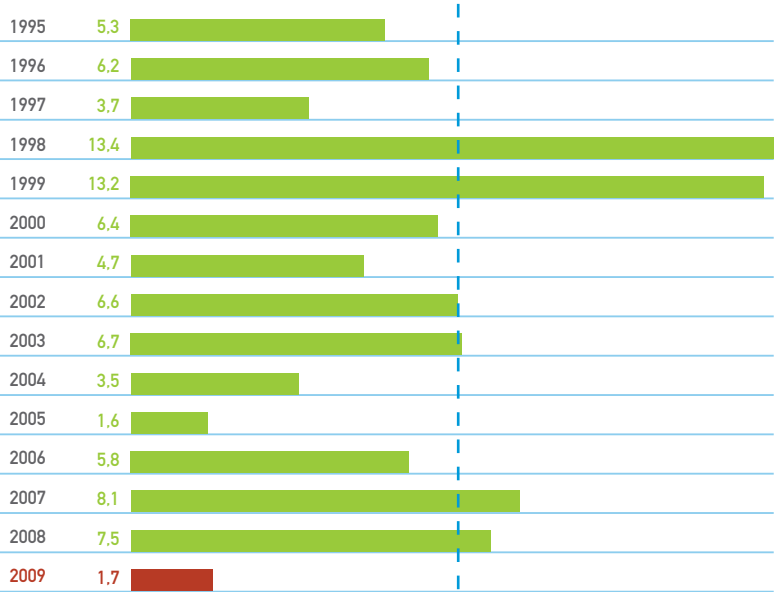


Image: fotolia

## 5.6.2 THE MARKET FOR REIMBURSABLE MEDICATIONS

### INCREASE IN EXPENDITURES FOR MEDICINAL PRODUCTS\*

In 2009, the expenditures of the health insurers for medicinal products increased by 1.7% compared to the year 2008.



in percent vs. preceding year

6.37 (=average)

Source: HV

\*Expenditure for medicinal products without VAT and before deduction of prescription charges

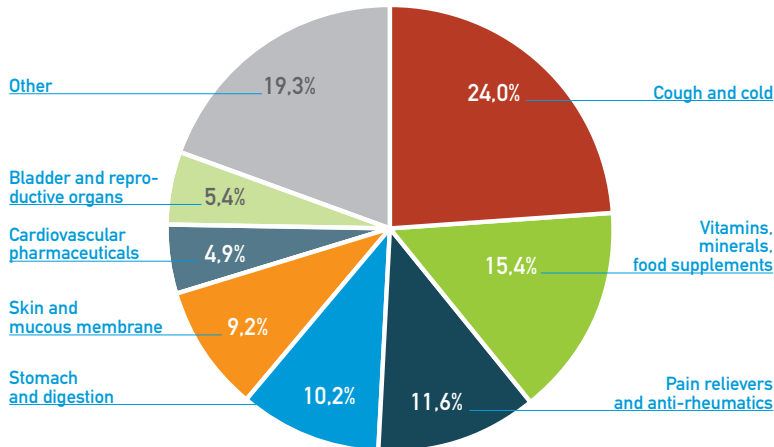
The market for reimbursable medicinal products, which is the market segment that includes medicinal products whose costs are assumed by the individual social insurance institutions, suffered a substantial slowdown in growth in 2005.

The main cause therefore was the implementation of the code of reimbursement with January 1, 2005.

## 5.6.3 OTC MARKET AND SELF-MEDICATION PRODUCTS

In 2009, the OTC market at pharmacy prices (Euro 525,7 million) was divided up as shown below: 6,9% prescribed non-prescription medicinal products, 58,4% self-medication with registered OTC products and 34,7% self-medication with non-registered OTC products.

INDICATION GROUPS IN SELF-MEDICATION 2009 (BASED ON PHARMACY SALES PRICE)



Source: IGEPHA, basis AVP

About a quarter of the sales in the self-medication market are made through the sale of cough and cold remedies.

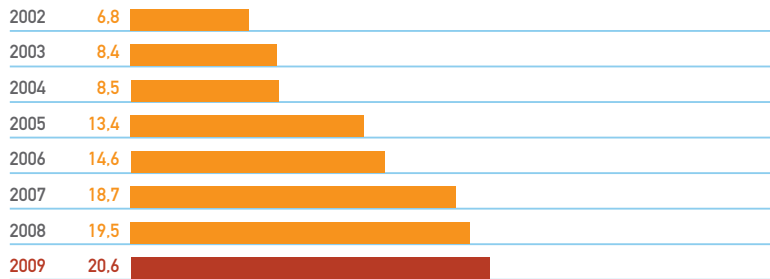


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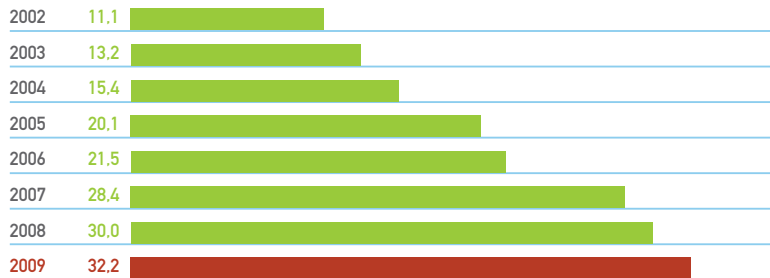
## 5.6.4 GENERICIS

### GENERICIS IN AUSTRIA

based on value



based on volume



in percent of reimbursable drug market

Source: IMS 2002/2003, 2005-2009, HV 2004

Generics are preparations sold as copies of original medicinal products after the patent for the originals has expired. They can be approved in a "referential" approval procedure (see Chapter 3) if there is no longer a patent protection or regulatory data protection for the original medicinal product.

In 2009, the market share of generics in the reimbursable drug market was 32,2% in volume and 20,6% in value (sales Euro 262 million, based on wholesale purchasing price).

The share of generics in Austria's market grew again in 2009.

# HEALTH INSURANCE INSTITUTIONS

# 6

A total of 22 social insurance institutions including 19 health insurance institutions (status: 2010) protect insured persons paying contributions (6,4 million; status: 2009) from the financial consequences of illness. Membership in these institutions is mandatory for those insured. Every insured person is a member of one of the 19 institutions, depending on their occupation and the location of the office. There is no choice (except for those who pursue more than one occupation). The individual health insurance funds are to a large extent managed autonomously. Besides the health insurances there are 16 medical care institutions („KFA“) for employess of several municipal and regional administrations, such as the KFA for the civil servants of the city of Vienna.

The overwhelming majority of services covered by the health insurance schemes are subject to the principle of benefit in kind. There exist numerous co-payments and additional fees which have, as of yet, not been harmonised. All together, in 2009, the health insurance institutions collected approx. 363 million Euro in prescription charges.

## ANNUAL CEILING ON PRESCRIPTION CHARGES

Since 1st of January 2008 an annual ceiling on prescription charges has been introduced to give some financial relief to people needing more and more medicines.

This ceiling is 2% of the annual net income (excluding special payments such as holiday or Christmas pay) of the person insured and is the highest amount that he will have to pay in prescription charges for himself and his co-insured dependants in the current calendar year. As soon as this amount is exceeded, the person insured and his co-insured dependants do not have to pay the prescription charges for the rest of the calendar year.

Austria provides statutory insurance for the gainfully employed population.

The 2% of the annual net income (exclusive of holiday and Christmas allowances) is calculated by the Social Security and is done as follows:

- in the case of employees, on the basis of the annual contribution base for the preceding year,
- in the case of pensioners, on the basis of the current net pension,
- in the case of those receiving payments under the Unemployment Insurance Act (ALVG), on the basis of the current payment,
- in the case of those who are self-insured, on the basis of contribution base or the equalisation supplement standard rate,
- in the case of the self-employed, on the basis of the income tax assessment.

To implement the new system, a prescription charge account is set up at the main association for each person insured, where the prescription charges paid in the current year (2011: 5,10 Euro per medicinal package prescribed) are entered and matched to the particular net income of the person insured (without taking into consideration the income of the co-insured).

If the prescription charge ceiling of 2% of the net income is exceeded, an automatic report of prescription charge exemption is sent to the e-card system. The next time the e-card is inserted in the doctor's surgery, the exemption from prescription charges is shown – however not the reason for the exemption – and noted on the prescription by the doctor or doctor's assistant. At the chemist's then, the person insured is not charged for the prescription. The exemption based on the prescription charge ceiling does not however lead to an exemption from a portion of costs for medical aids and tools (e.g. glasses, crutches, wheelchairs).

The minimum ceiling in 2011 is around 190.40 Euro or 38 prescription charges. This corresponds to 2% of twelve times the individual standard rate for the equalisation supplement (2011: 793,40 Euro monthly).

As a result, every person insured, who is not exempt from the prescription charge as a result of the need for social protection, must pay for at least 37 prescription charges, before he is exempt from paying the prescription charge for the rest of the calendar year because the prescription charge ceiling has been reached.

#### SAMPLE CALCULATION FOR AN EMPLOYEE

Net income in the calendar year 2010:

Euro 1.000,- x 12 = Euro 12.000,-

Ceiling for prescription charges:

2% of Euro 12.000,- = Euro 240,-

Reaching the ceiling:

Euro 240,- : Euro 5,10 (prescription charge 2011) = 47

On the basis of the new prescription charge ceiling, the person insured is exempt from paying the prescription charge from the 47<sup>th</sup> prescription in the current year.

Every insured person must pay at least 38 prescription charges before reaching the annual ceiling for prescription charges.

## 6.1 CODE OF REIMBURSEMENT (EKO)

Effective January 1, 2005, the previous reimbursement list was replaced by a Code of Reimbursement (Erstattungskodex or EKO).

A print version of the whole EKO is published at the beginning of every year (contains the green and yellow boxes), any monthly changes (also in the red box) are published online at [www.avsv.at](http://www.avsv.at).

### THE EKO CONSISTS OF THREE GROUPS (ALSO CALLED BOXES):

- The **GREEN BOX** comprises medicinal products which are either general dispensable or under specific circumstances in specified amounts. The authorisation of a chief consultant (control physician) belonging to the health insurance is not required if the rules of the Code of Reimbursement are complied with.
- The **YELLOW BOX** box includes all those medicinal products which exhibit an essential additional therapeutic benefit for the patient and which are not included in the green area for medical and/or reasons of health economy. The costs are only reimbursed by the health insurance upon presentation of a medical approval by a chief consultant (control physician) of the insurance fund (RE1 = dark yellow box). For specific medicinal products in this box, whose inclusion relates to a specific application, the Main Association provides for a follow-up verification of compliance with the specified application (using the documentation provided by the attending physician) instead of the approval by a chief consultant (control physician; RE2 = light yellow box).
- The **RED BOX** temporarily comprises all medicinal products for which an application for inclusion in the Code of Reimbursement was submitted. The costs are assumed by the health insurance only upon presentation of a medical approval by a chief consultant (control physician) of the insurance fund.

Furthermore, the EKO also contains the list of substances for pharmacist's preparations which may only be dispensed upon prior presentation of the medical approval by a chief consultant (control physician).

All other medicinal products not included in the Code of Reimbursement are only reimbursed in justified cases and upon presentation of the medical approval by a chief consultant (control physician). Specific groups of medicinal products, such as for contraception, must be paid by the patient in all cases.

A differentiation is made between green box, dark yellow and light yellow box and red box.

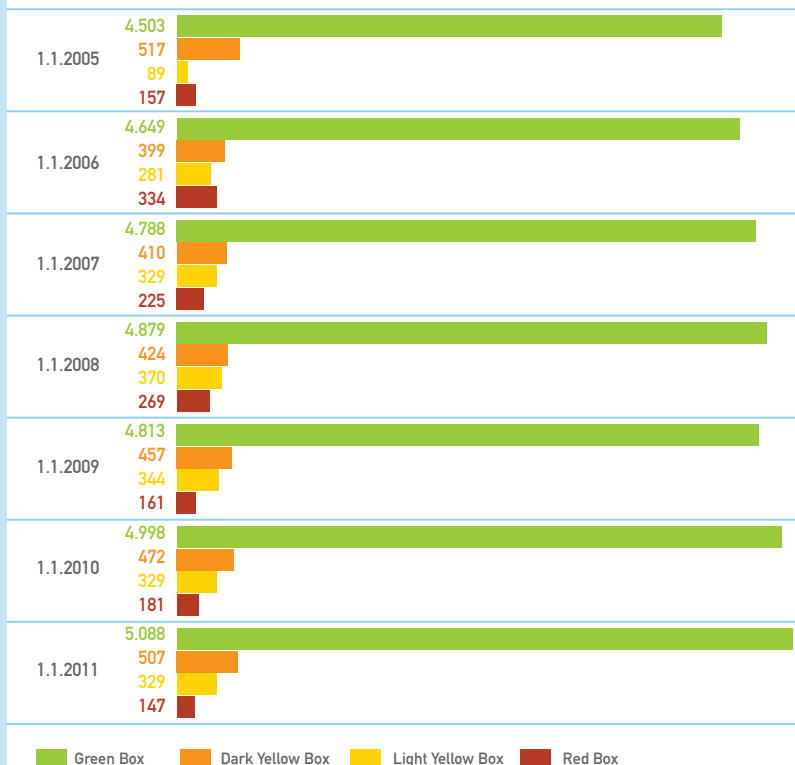
### ATC CODES: ANATOMIC THERAPEUTIC CHEMICAL CLASSIFICATION

The ATC classification groups active agents in accordance with the organ or the system of organs which they affect and according to their chemical, pharmacological and therapeutic properties. Since 1982, the ATC system has been further developed and revised by the WHO Collaborating Centre for Drug Statistics Methodology (<http://www.whocc.no>) in Oslo, as central coordination office. An update is published once a year.

The seven-digit ATC code is put together in five stages. The first stage indicates to which of the 14 main anatomical groups a medicinal product belongs and is expressed by a letter of the alphabet. The second stage consists of two digits and indicates the therapeutic sub-groups. The third stage indicates the pharmacological sub-groups as a letter from the alphabet and the fourth indicates the chemical sub-group, also by way of a letter. The fifth stage consists of two digits and represents the chemical agent.

### NUMBER OF MEDICINAL PRODUCTS IN THE EKO (ACC. TO NATIONAL DRUG CODE)

On January 1, 2011,  
6.071 packages  
were listed in EKO.



Source: 2005-2009/2011 HV, 2010 Pharmacy index of goods

When the EKO was introduced, it listed a total of 5.266 packages, by January 1, 2011 the number had increased to 6.071.

**ABS (PHARMACEUTICAL APPROVAL SERVICE) AND "OBLIGATION FOR APPROVAL BY CHIEF PHYSICIAN"**

In the course of the e-card roll-out, all resident physicians with a valid contract (general practitioner, specialists, dentists), institutes and out-patient clinics with contracts (no hospitals), separate institutions of the social insurance providers and secondary offices of physicians (provided they have concluded a contract) are equipped with the ABS system (pharmaceutical approval service).

The scope of treatment for an illness at the expense of the social insurance provider is defined by law as follows:

"It must be sufficient and purposeful, but should not go beyond what is necessary". (§ 133 ASVG)

In the indications for which prescribable medicinal products are freely available but do not suffice for the treatment of an illness as unanimously agreed by the attending physician and the chief consultant (control physician), the health insurance also assumes the costs for other therapy alternatives. This includes the most modern and most innovative medicinal products.

Before the health insurance physician may prescribe a patient any medicinal product that requires approval, he must place an electronic request with the chief consultant (control physician) of the health insurance. Using the e-card infrastructure available (ABS), this process should take no longer than 30 minutes. Only when the health insurance physician has received the "okay" from the health insurance, is he permitted to write a prescription. If the request is rejected, the physician can submit an additional request with more justification. If the health insurance finally rejects the request, the only option left for the patient is to buy the medicinal product in the pharmacy at his own expense.

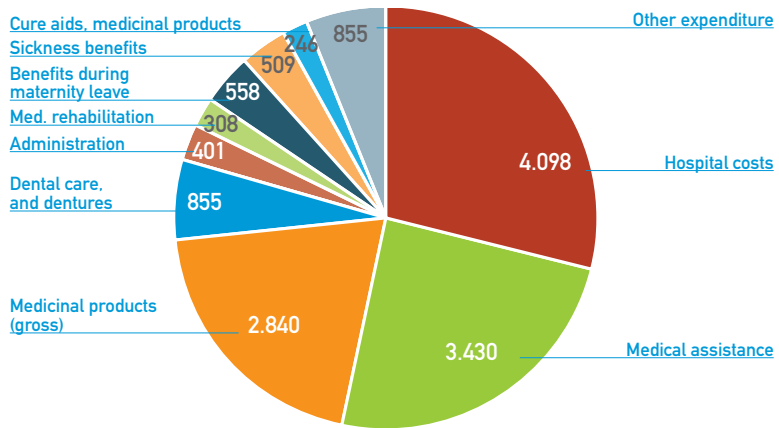
The patient, however, is legally entitled to ask the health insurance to provide a written notification of rejection. The patient can then lodge an appeal against this notification with the responsible labour and social court.

The pharmaceutical approval service, ABS, aims at simplifying the approval applications.

## 6.2 PHARMACEUTICAL EXPENDITURES AND POLICIES OF HEALTH INSURANCE INSTITUTIONS

The item „Medicinal products (gross)” is inclusive VAT and does not include prescription charges.

### POLICIES OF HEALTH INSURANCE INSTITUTIONS 2009



Total expenditure	14.100
-------------------	--------

Total revenue	14.269
---------------	--------

in Euro million Source: HV

The revenues of social insurance schemes amounted to Euro 14.269 million (+ 4.3%) in 2009, and their expenditure amounted to Euro 14.100 million (+ 2.4%). The earnings therefore amounted to EUR 169 million.

### NET EXPENDITURES FOR MEDICINAL PRODUCTS 2004 - 2008

Values in Euro million	2005	2006	2007	2008	2009	2009 vs. 2008
Gross value medicinal products	2.463	2.606	2.822	3.031	2.840	-6.3%
Net value (w/o VAT)	2.060	2.180	2.357	2.533	2.575	+1.7%
Revenue from prescription charges	-343	-371	-393	-385	-363	-2.2%
Net expenditures med. products	11.717	1.809	1.964	2.148	2.212	+3.0%

Source: HV

## 6.3 PRESCRIPTION TRENDS

In 2009, the number of reimbursed prescriptions was 117.080.832.

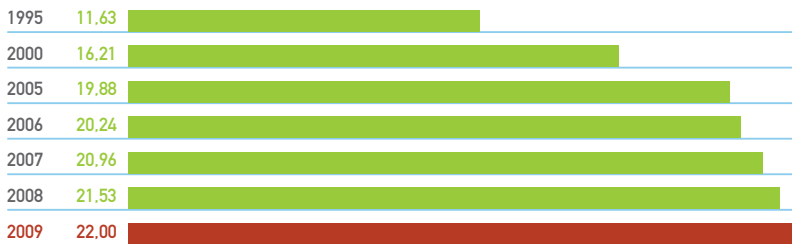
### PRESCRIPTION TRENDS

Number of reimbursed prescriptions in million



The number of prescription decreased by 0,5 % in 2009.

Value for each reimbursed prescription in Euro

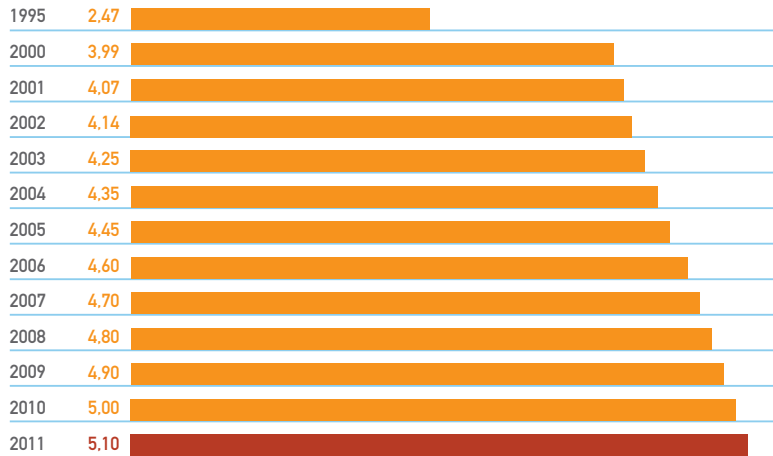


The value per prescription increased by 2,1% in 2009.

Source (both graphics): HV

## 6.4. PRESCRIPTION CHARGE AND DEDUCTIBLE

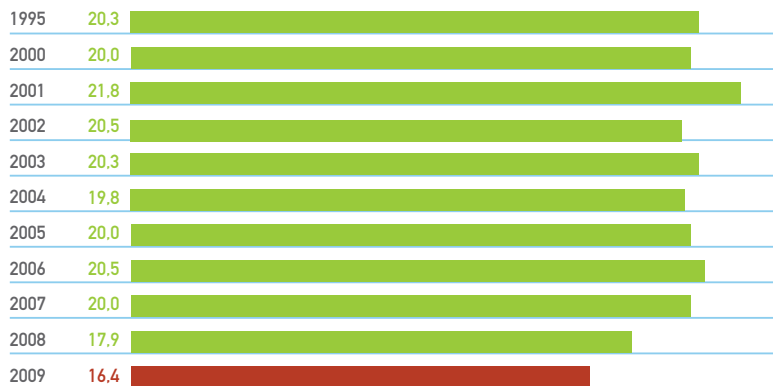
### DEVELOPMENT OF PRESCRIPTION CHARGE



in Euros

Source: annual publication of prescription charge

### DEDUCTIBLE FOR MEDICINAL PRODUCTS



in percent

Source: HV

Increase in prescription charge since 2000 compared to 2011: + 27.8%

When setting the net expenditures of health insurance funds for medicinal products (2.212 million Euros) off against the prescription charge revenue (363 million Euros), a deductible of 16.4% remains which is to be paid for the medicinal product by the patient.

# HOSPITALS IN AUSTRIA

# 7

In Austria, hospitals totalled 267 in 2009.

The hospital system is of federal nature, i.e. the jurisdiction is with the provincial governments.

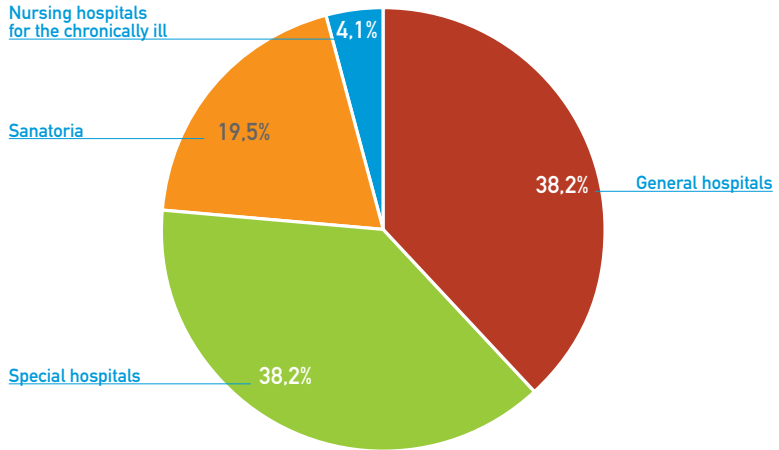
The legal basis for all hospitals is the Federal Hospitals Act (KAKuG). This Act serves as the basis for the 9 provincial acts, which represent implementing statutes.

Hospitals as per § 2 of the Federal Hospitals Act include:

1. **GENERAL HOSPITALS:** For persons irrespective of their gender, age or the type of medical care they receive.
2. **SPECIAL HOSPITALS:** For the examination and treatment of persons with specific diseases or of persons of a particular age or for certain purposes.
3. **HOMES FOR CONVALESCENT:** Persons requiring medical treatment and special care.
4. **NURSING HOSPITALS FOR CHRONICALLY ILL:** Persons requiring medical treatment and special care.
5. **CHILDBIRTH HOSPITALS** (this type of hospitals existed in Austria only until 2000)
6. **SANATORIA:** Hospitals with special equipment for special care and accommodation.
7. **INDEPENDENT OUT-PATIENT CLINICS:** Independent institutions (e.g. X-ray institutes, dental clinics) for the examination and treatment of persons who do not require in-patient treatment.

In Austria, hospitals fall within the jurisdiction of the provincial governments.

**TYPES OF HOSPITALS (WITHOUT INDEPENDENT OUT-PATIENT CLINICS) 2009**



Source: Statistics Austria, BHG

## 7.1 STRUCTURAL DETAILS OF HOSPITALS

Approx. 58% of hospitals are run by public agencies and institutions.

Of these 267 hospitals, 128 (47.9%) are hospitals with public status and 139 (52.1%) without public status. Hospitals with public status are not to be confused with hospitals of public agencies and institutions (155).

**OWNERSHIP/RESPONSIBLE BODIES – PUBLIC LAW STATUS IN 2009**

Number of hospitals and beds actually set up		
	With public law status* 155 hospitals (45.778 beds)	Without public law status** 112 hospitals (18.291 beds)
Public ownership 128 hospitals (46.715 beds)	103 hospitals (39.424 beds)	25 hospitals (7.291 beds)
Private ownership 139 hospitals (17.354 beds)	52 hospitals (6.354 beds)	87 hospitals (11.000 beds)

\* federal government, provincial and municipal hospital companies, social insurance institutions  
 \*\* religious orders and congregations, private persons, private companies and associations

Source: BMG

The overview also indicates the actually set up beds in Austria's hospitals (64.069 beds). In relation to Austria's population, the bed coverage was 7,6 beds per 1.000 inhabitants.

In Austria there are a total of 64.069 beds.

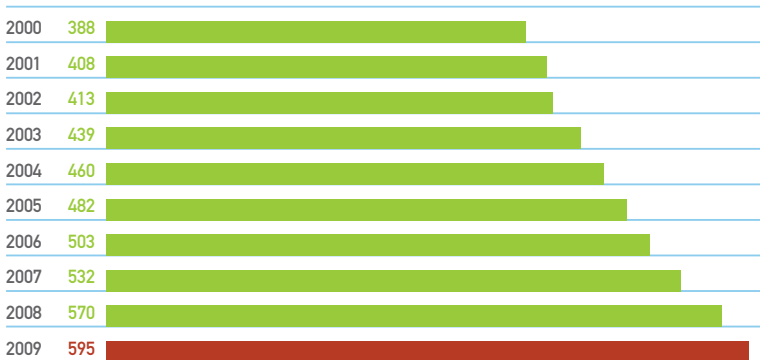
#### DEVELOPMENT OF BED CAPACITY IN AUSTRIA PER 1.000 INHABITANTS

	Bed coverage	thereof financed by provincial health funds
2000	7,95	79,6%
2001	7,85	79,6%
2002	7,80	79,1%
2003	7,74	78,5%
2004	7,73	77,7%
2005	7,68	77,4%
2006	7,65	77,1%
2007	7,76	75,9%
2008	7,71	75,6%
2009	7,64	75,9%

In 2009, 2,8 million hospitalisations for in-patient treatment were reported in Austrian hospitals. The hospitalisation frequency (=hospital stays per 100 inhabitants) amounted to 33,4% (1991: 23,9%, 2005: 31,8%).

The average duration of hospitalisation in hospitals financed by provincial health funds was 5,5 days in 2009.

#### DEVELOPMENT OF PER-DAY COSTS OF IN-PATIENT STAYS IN HOSPITALS FUNDED BY PROVINCIAL HEALTH FUNDS



in Euros

Source: BMG

## 7.2 HOSPITAL FUNDING

The expenditure of Austrian hospitals operating on the LKF basis (system of performance-oriented hospital financing) amounted to 10.692 million Euro in 2009. Of these, about 60% were funded by the Provincial Health Fund. The remainder had to be paid by the hospital operators using other means. Patients also directly contributed to the funding, e.g. through private insurances.

### THE MOST IMPORTANT PAYERS FOR HOSPITALS FINANCED THROUGH THE PROVINCIAL HEALTH FUND IN 2009

	Euro Millions
Share from provincial funds	6.266
Social insurance	4.110
The federation	1.055
Federal provinces (VAT-funded)	183
Municipalities (VAT-funded)	130
Funder means	788
Share from hospital funders	3.326
Federal provinces, municipalities	1.838
Religious orders and others	1.405
Social insurance	83
Share from private parties	1.100
Patients, private insurances	1.100
<b>TOTAL</b>	<b>10.692</b>

Source: IPF

Social insurance contributes a large share to hospital funding.



## 8

# PREVENTIVE HEALTH

Within the area of prevention, one can differentiate between

- **PRIMARY PREVENTION**  
(promotion of a healthy lifestyle, prevention of diseases),
- **SECONDARY PREVENTION**  
(early detection of existing diseases/risks) and
- **TERTIARY PREVENTION**  
(delaying the disease course, prevention of relapses, reduction of secondary damage).



Bild: istock

## PREVENTIVE CHECKUPS IN AUSTRIA

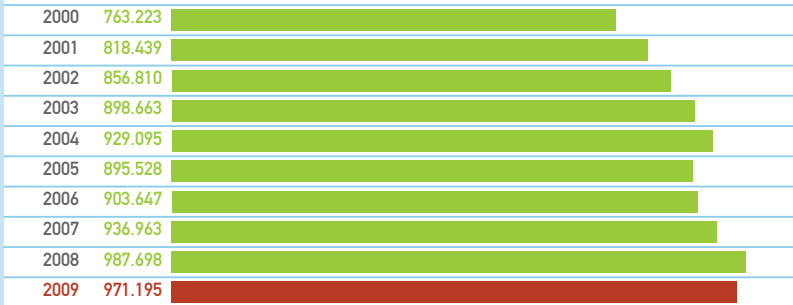
All Austrians are entitled to an annual preventive checkup (in the case of uninsured persons, the Federal Government reimburses the health insurance companies for the costs).

While the basic examination serves to establish a medical history of the patient and detect endemic diseases as early as possible, there are also more specific checkup programmes for women (pelvic examinations, mammography) as well as targeted screenings for people over a certain age.

Everybody can benefit from preventive checkups.

About 90% of the preventive checkups are basic examinations.

**BASIC EXAMINATIONS AND PELVIC EXAMINATIONS**



Quelle: HV

In 2009, 971.195 people attended basic examinations (839.360) or rather pelvic examinations (131.835).

Looking only at the gender breakdown of the basic examinations in Austria in 2009 (839.360), women make up a slightly larger proportion with 53%.

Compared between the individual states, in 2009 Vienna is the leader in preventive examinations with about 19%, followed by Tyrol with around 17%.



Source: HV

# PHARMIG CODE OF CONDUCT

# 9

Since 1970, the Pharmig Code of Conduct (CoC) lays down what is allowed and what is prohibited when dealing and communicating with lay people, physicians and members of other healthcare-related occupations. This voluntary self-restriction of the pharmaceutical industry goes beyond the legal framework conditions and is an expression of the great responsibility of the industry. In a comprehensive amendment in 2007, the provisions of the CoC were further tightened and the procedural rules of the CoC redesigned. The CoC is stricter than comparable regulations in other European countries or the code of the European industry association EFPIA and includes both prescription and OTC medicines.

In addition to the General Principles, the Code contains rules governing the information about pharmaceuticals, advertising of pharmaceuticals, information and advertising over the Internet, events, collaboration with professionals or third parties, gifts, raffles, company employees, clinical trials and violations of the Medical Product Act (MPA). In 2009 the regulations concerning the cooperation with patient organisations were included in the Code of Conduct. The Code is principally based on the provisions of the MPA, but also includes topics not covered in the MPA. In the consistent pursuit of quality and transparency in the collaboration between the pharmaceutical industry and the health professionals, Pharmig provided the CoC Regulation of non interventional studies. With 1st of March 2010 the regulation entered into force.

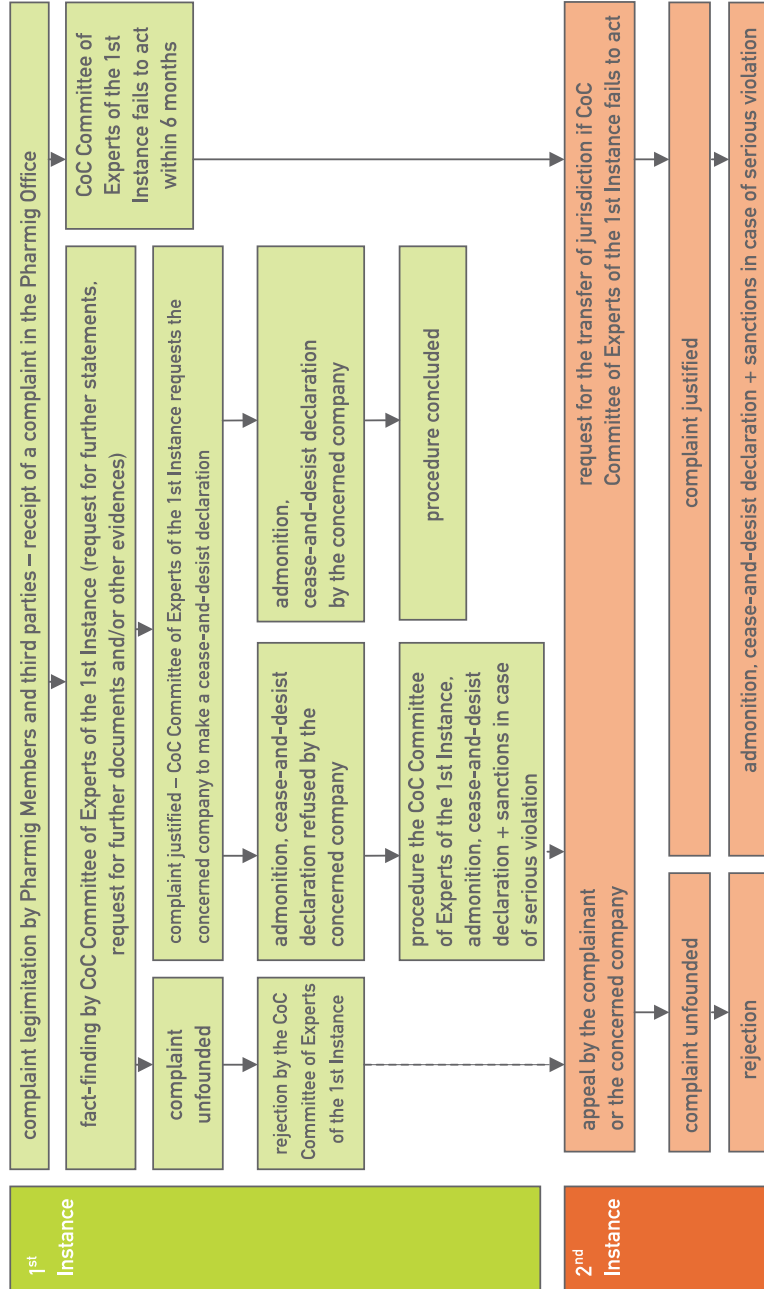
All member companies of Pharmig have agreed to the provisions of the CoC and have dedicated themselves to the regulations. Furthermore, non-members also have the opportunity to join the voluntary self-restriction. If a third party wants to file a complaint because of a CoC infringement, the party must also join the CoC for the specific case. Complaints concerning violations of Article 7 (events) and Article 9 (gifts) may also be filed anonymously.

Looking at the past year, there were a total of two CoC complaints submitted in 2010 (there was one anonymous complaint). Additionally, six complaints procedures from 2009 had been completed.

In 2010, two CoC complaints were filed.

FLOWCHART

PROCEDURE OF THE CoC COMMITTEES OF EXPERTS OF THE 1ST AND 2ND INSTANCE



## 10

# LAWS AND REGULATIONS

The table below lists the major laws relating to the development, production, evaluation, marketing authorisation and the distribution of medicinal products.

LAW	SCOPE OF APPLICABILITY
Medicinal Products Act	Definitions, clinical trials, marketing authorisation, manufacture, distribution, advertising, pharmacovigilance, approval of plant and equipment
Austrian Medicine Import Act	Import and distribution of medicinal products
Prescription Act	Prescription status
Narcotic Substance Act	Narcotics status, charges and placing on the market
Act Against Unfair Competition (UWG)	Advertisement with regard to consumers and competitors
Industrial Code	Right to run a pharmaceutical company
Pharmacopoeia Act	Quality and testing of medicinal products
Price Act	Pricing and (by ordinances) maximum mark-ups (margins)
Price Transparency Act	Price increases
Health and Food Safety Act	Spin-off of responsibilities and procedures reg. the medicinal product system from the BMG to AGES PharmMed
Patent Protection Act	Patent protection also of medicinal products
Federal Hospitals Act (KAKuG)	Forms the legal basis for all hospitals and the foundations for the 9 provincial laws, which represent implementation statutes
General Social Insurance Act (ASVG)	Governs the General Social Insurance for persons employed in Austria, incl. the self-employed persons who have an equal standing and the health insurance of retirees from the General Social Insurance. The General Social Insurance comprises health insurance, accident and pension insurance with the exception of specific special insurances.
EU „Medicines Community Code“ (dir. 2001/83/EC)	Definitions, marketing authorisation and procedures, manufacturer and importation, labelling and package leaflet, wholesaling, advertising and information, pharmacovigilance
EU Transparency Directive (dir. 89/105/EEC)	procedural provisions, timelines and transparency rules for national decisions regarding reimbursement and prices

**REGULATIONS****SCOPE OF APPLICABILITY**

Ordinance on the Retail of Medicinal Products		Definition of pharmacies and drug stores as distribution channels
Narcotic Substances Ordinance		Distribution of narcotic-containing medicinal products
Summary of Product Characteristics Ordinance		Structure of the summary of product characteristics
Patient Information Leaflet Ordinance		Structure of the patient information leaflet
Ordinance on the Labelling of Products		Structure of labelling/outer packaging
Pharmacovigilance Ordinance		PV responsibilities of the marketing authorisation holder, notification of side effects and incidents
Ordinance on pharmaceutical representatives		Authorisation and testing of pharmaceutical representative
Ordinance for Companies Producing Medicinal		Products Corporate requirements for pharmaceutical companies
Fee Tariff Ordinance		Governs the tariffs for activities of the BASG (e.g. marketing authorisations, inspections)
Ordinance on the Authorisation and Control of Medicinal Products		Ordinance setting forth the principles of approval of medicinal products by chief consultants and control physicians, follow-up control of prescriptions and documentation principles
Rules of procedure for the publication of the Code of Reimbursement acc. to § 351g ASVG (VO-EKO)		Rules of procedure published by the Main Association of Austrian Social Insurance Institutions
Procedural Cost Ordinance pursuant to § 351g Abs. 4 ASVG (VK-VO)		Governs the amount of flat-fee cost rates for applications for a procedure in connection with the EKO
Ordinance on NIS		compulsory registration of NIS before implementing (since 01.09.2010)

**OTHER LEGAL REGULATIONS****SCOPE OF APPLICABILITY**

Good Clinical Practices	GCP	Guidelines on clinical trials
Good Manufacturing Practices	GMP	Guidelines on the manufacture of medicinal products
Good Laboratory Practices	GLP	Guidelines on the evaluation of medicinal products
Good Distribution Practices	GDP	Guidelines on logistics for medicinal products
Declaration of Helsinki		Duties of the physician (e.g. in clinical trials)
Code of Conduct	CoC	Rules for the information and advertisement policy of pharmaceutical companies
EU average prices acc. to ASVG		Governs the procedure of the price commission when determining the EU average price pursuant to § 351c (6) ASVG
Guidelines for the consideration of economic principles in patient treatment	RöK	The guidelines of the health insurance institution providing medical assistance, benefits equal to medical assistance, measures taken in the context of such benefits, the dispensation of curing aids by contractual partners other than pharmacies and dispensing doctors, which are to be considered suitable, purposeful and not going beyond what is necessary. Also includes the measures which are to ensure compliance with these principles.
Guidelines for the economic prescription of medicinal products and curing aids	RöV	Cost guidelines of the health insurance
Principles of the HEK (Medicinal Product Evaluation Commission)		Includes information on HEK relating to economic evaluation criteria, package sizes, follow-up controls and principles for the verification of deliverability in the red box of the EKO
Ordinance on NIS	CoC	contains planning, inspection, authorization of non interventional studies; relevant for pharmaceutical companies who plan, implement, inspect/or finance a NIS

## 11

# ABBREVIATIONS

ABS	Arzneimittel-Bewilligungs-Service (pharmaceutical approval service)
acc.	according
AGES	Agency for Health and Food Safety
ASVG	General Social Insurance Act
ATC Code	Anatomic Therapeutic Chemical Classification System
aver.	average
BASG	Federal Agency for Safety in Health Care
BMG	Federal Ministry for Health
CPI	Consumer price index
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EKO	Code of Reimbursement
EU	European Union
GDP	Gross domestic product
GESG	Health and Food Safety Act
HEK	Medicinal Products Evaluation Commission
HV	Main Association of Austrian Social Security Institutions
IGEPHA	The Austrian Self-Medication Industry
IMS	IMS Health
IPF	Institute of Pharmaco-economic Research
LKF	Performance-oriented hospital financing
MAH	Marketing Authorisation Holder
MPA	Medicinal Product Act
OECD	Organisation for Economic Cooperation and Development
OTC	Over The Counter
PharmMed	Division of AGES
PhRMA	Pharmaceutical Research and Manufacturers of America
PV	Pharmacovigilance
R&D	Research & Development
SPC	Supplementary Protection Certificate
UHK	Independent Medicinal Products Commission
VAT	Value-added Tax
WKÖ	Austrian Federal Economic Chamber

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