PHARMIG

Verband der pharmazeutischen Industrie Österreichs

Facts & Figures 2017

Medicinal Products and Health Care in Austria

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Imprint

Owned and published by
Dr. Jan Oliver Huber, Secretary General
Pharmig, Association of the Austrian
Pharmaceutical Industry
Garnisongasse 4/2/8, 1090 Wien

Phone: +43 1 4060 290, Fax: +43 1 4060 290-9
E-mail: office@pharmig.at
Web: www.pharmig.at
ZVR-number: 319425359

Editorial staff
Mag. Julia Girardi
Simone Farina, Bakk. Komm.

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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 2015/2016.

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.

Pharmig at a glance

Pharmig – the associaton of the Austrian pharmaceutical industry – is a voluntary and party-politically independent representation of interests of the pharmaceutical industry in Austria.

Pharmig represents about 120 member companies with approximately 18,000 employees in total. These companies make up more than 95 per cent of the medicinal product market.

Pharmig and its member companies are committed to secure supply of medicinal products in the health care system to the best effect. Through quality and innovation Pharmig and its member companies ensure both social and medical progress.

The pharmaceutical industry is dedicated to strengthening Austria's role as a pharmaceutical and research location. It constitutes an excellent example for the successful cooperation of economy and science which ultimately aids the further development of our knowledge society.

As a recognised and competent Partner, Pharmig uses its great expertise to support decision makers in the healthcare system and relevant policy areas. In so doing, Pharmig demands fair, reliable and calculable framework conditions for the pharmaceutical industry which support all stake holders and the entire population.

It is the primary aim of the association and of the businesses of the pharmaceutical industry to ensure the best possible supply of medicines for the population of Austria.

Dear Reader!

Photo: Photo Simonis

I am delighted to be able to present you the latest issue of Facts & Figures. Here we provide you with comprehensive health care information.

The reference work Facts & Figures is growing. We have prepared and included a few new topics for you this time as well:

- **Achievements of innovative therapies**
  Our industry stands for innovation. Thanks to innovative therapies, more and more illnesses can be healed and more and more people affected by illness are at least living with a better quality of life. In the "Pharmaceutical Research and Development" chapter, you will find data about the outstanding achievements of new therapies, specifically in oncology, for HIV/aids and for hepatitis C.

- **Status quo serialisation of medicinal products**
  In the "Marketing Authorisation for Medicinal Products" chapter, you can read what has happened in Austria with the implementation of the European Falsified Medicines Directive. Among other things, the AMVO, the Austria Medicines Verification Organisation, was established in the previous year. This organisation is responsible for the governance of the medicinal product verification system.

- **Health care reforms**
  The public health care system in Austria suffers from structural imbalances and is therefore one of the most cost intensive in the European Union. The reform efforts that have existed since the middle of the 2000s are summarised clearly for you in the "Health Care System in Austria"chapter.

The English version "Facts & Figures" is available to download from our website www.pharmig.at, in the Publications section.

I hope you enjoy reading and learning from our new Facts & Figures!
Best wishes,

Dr. Jan Oliver Huber
Secretary General, Pharmig

1 Health Care System in Austria

The Austrian health care system is affected by the federalist structure of the country. Through the multitude of decision-makers (federal, state, municipality, social insurance), health care financing is not regulated from one source, but rather depends on multiple sources of financing (including taxes, social insurance premiums through social insurance, federal, state, municipality, etc. See Chapter 1.3). Agreement among those responsible is important due to the fragmented responsibilities. An important general framework therefore determined in mutual agreements and contracts (for example, agreements according to Art. 15a Austrian Constitutional Law – B-VG).

1.1 Economic basic information

The population of Austria in 2015 was 8.700.471. 99 % are protected by one of the 21 social insurance institutions (status 2017), in addition to 15 special health care institutions (see Chapter 1.4).

1.2 Social expenditures

Social expenditures in total amounted to Euro 99.90 billion in 2015. 70 % of social expenditures consist of retirement benefits and health care services.

Social Expenditures* acc. to function in 2015

	Mio. Euro	Prozent
Age	44,226.32	44.3
Illness/health care	25,416.71	25.4
of which sickness benefits	685.42	0.7
of which continued payment of wages during illness	2,839.70	2.8
of which in-patient care	11,825.23	11.8
of which out-patient care	8,796.26	8.8
of which prevention of illness/rehabilitation	971.15	1.0
of which other benefits in cash/in kind**	298.94	0.3
Family/children	9,621.32	9.6
Surviving dependants	6,046.15	6.0
Invalidity/disability	6,703.22	6.7
Unemployment	5,635.91	5.6
Habitation and social exclusion	2,290.37	2.3
Total	**99,940.00**	**100**

Source: Statistics Austria

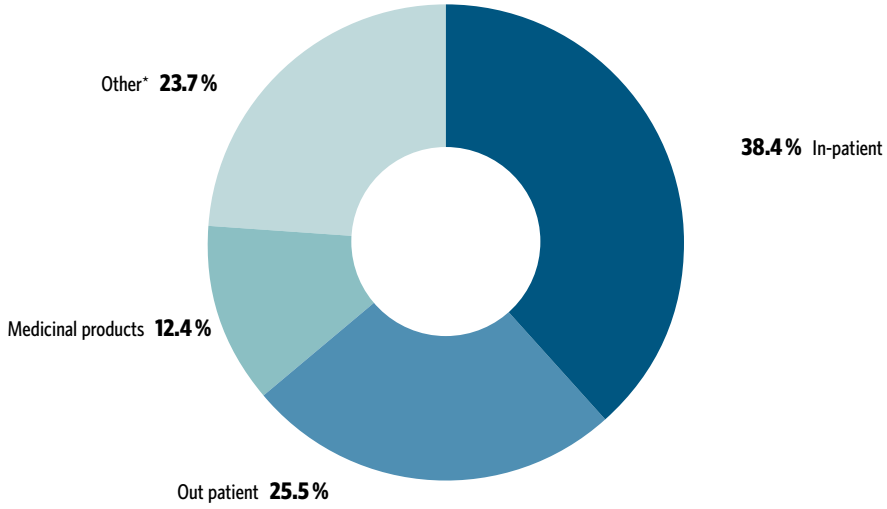
* social expenditures of functional organization are the sum of social beneftis, without transfers between social systems (redirected social contributions and other transfers) and without other expenditures (administrative expenses, other not attributable expenditures)

** other social benefits: treatments for accidents, benefits in cash from other health care institutions, benefits in kind from welfare/minimum income; data from 2000 onwards can only partially be compared to earlier data.

1.3 Health care expenditures

According to the "System of Health Accounts" (SHA), health expenditure consists of running health costs and investments in the healthcare sector.

In 2015, health expenditures in Austria amounted to some Euro 37.6 billion, which corresponds to a share in GDP of 11.1 %.



Source: calculated by the Institute of Pharmaeconomic Research (IPF) with reference to the following data: IMS, Austrian statistics, HV

* Expenditures for long-term care, ambulance services, public health services, administration, medical products and equipment, private insurance.

The largest proportion of 38.4 % was spent on in-patient care. At the same time, expenditure on out-patient care made up 25.5 % and expenditure on medicinal products 12.4 %.

Expenditure on medicinal products includes consumption in pharmacies and hospitals, incl. VAT. The proportion between expenditure on medicinal products and total health expenditures in % is defined as the pharmaceutical ratio.
The pharmaceutical ratio also mirrors the varying significance of the healthcare settings (in-patient, out-patient, drug therapy) at national level.

Health care financing	2013		2014	
	Euro Mill.	Percent	Euro Mill.	Percent
Public health care financing	27,081	74.2	27,870	74.2
In-patient care*	11,816	32.4	12,172	32.4
Out-patient care	6,386	17.5	6,642	17.7
Long-term care at home**	2,344	6.4	2,357	6.3
Ambulance and emergency medical services	356	1.0	363	1.0
Pharmaceutical products, medical equipment	3,509	9.6	3,672	9.8
Prevention and public health services	522	1.4	555	1.5
Health care administration: State incl, social insurance	722	2.0	752	2.0
Public investments	1,425	3.9	1,357	3.6
Private health care financing	9,404	25.8	9,708	25.8
In-patient care*	2,219	6.1	2,256	6.0
Out-patient care	2,862	7.8	2,956	7.9
Pharmaceutical products, medical equipment	2,186	6.0	2,240	6.0
Health care administration private insurance	547	1.5	569	1.5
Investments (private)	1,073	2.9	1,144	3.0
Non-profit private organisations	458	1.3	481	1.3
Services provided by company physicians	60	0.2	63	0.2
Total	**36,485**	**100**	**37,578**	**100**

Source: Statistics Austria

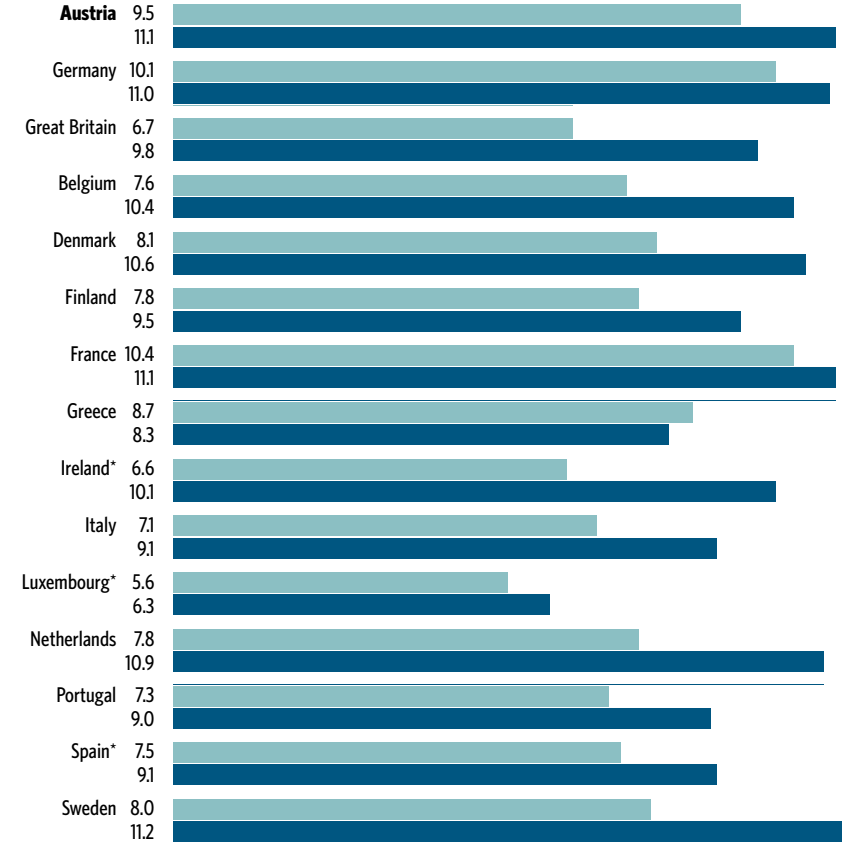
* Includes in-patient health care services in nursing homes.

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

When broken down into public and private expenditure on health care, nearly three-fourths of the expenses are financed by public funds. In the period between 2010 and 2015, expenditure on health care rose on average by 3 % each year.

Comparative health care expenditures

Health care expenditure in % of GDP[1]



[1] graphical illustration of selected OECD countries

1995 2015

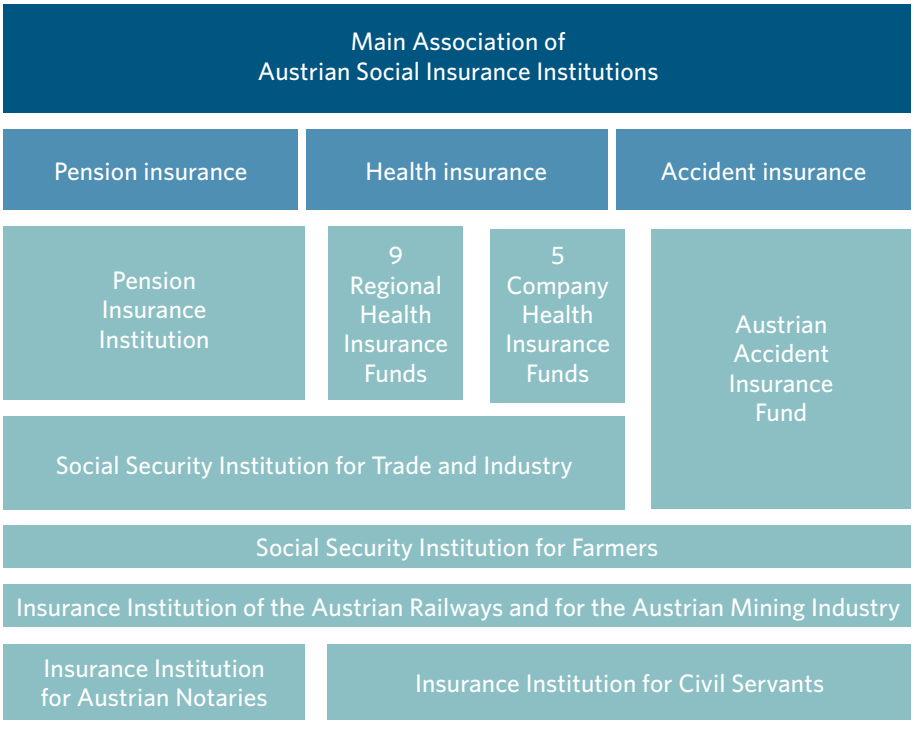
Source: Statistics Austria, OECD

* 2011

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. 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).

1.4 The social security system

The Austrian system of social security



Source: HV

The 21* social insurance institutions are coordinated by the Main Association of Austrian Social Insurance Institutions.

- Pension insurance
- Health insurance ("health insurance funds")
- Accident insurance

Everyone is compulsorily insured with the respective institution for their branch of industry or with their competent Regional Health Insurance Fund. The statutory health insurance system allows for multiple insurance. In addition to the health insurance funds 15 special health care institutions provide health insurance for employees working in regional or municipal administration (see page 9).

* Liquidation BKK tobacco per 01/2017

Development of persons entitled to claim against a health insurance policy by insurance provider

Annual average 2010/2015	2010	2015
Total* persons	**8,131,341**	**8,506,925**
All insurance providers (insurance ratio)**	**8,758,839**	**9,205,.527**
Regional health insurance fund – Vienna	1,512,870	1,644,907
Regional health insurance fund – Lower Austria	1,138,826	1,195,355
Regional health insurance fund – Burgenland	191,620	207,796
Regional health insurance fund – Upper Austria	1,165,286	1,216,485
Regional health insurance fund – Styria	899,042	943,210
Regional health insurance fund – Carinthia	419,963	431,930
Regional health insurance fund – Salzburg	439,052	456,768
Regional health insurance fund – Tyrol	551,444	579,664
Regional health insurance fund – Vorarlberg	307,763	320,084
Company health insurance fund Austria Tabak BKK	3,093	1,912
Company health insurance fund Transport companies	19,458	19,650
Mondi	2,852	2,591
Company health insurance fund VABS	12,994	13,034
Company health insurance fund Zeltweg	4,218	4,218
Company health insurance fund Kapfenberg	9,975	9,967
Insurance Institution of Austrian Railways and Mining Industry	247,116	223,251
Insurance Institution for public servants	757,620	794,751
Social Security Institution for Trade and Industry	694,567	779,051
Social Security Institution for Farmers	381,080	360,903

in absolute Source: HV

* Each individual is counted once.

** The statistics do not count the number of persons with health insurance but rather the health insurance ratios. Persons with more than one insurance provider are counted once with each insurance provider.

Number of employees in health insurance institutions

Annual average 2015	Number of staff in total	Administration and invoicing	General medical services	Special institutions*
Total	**13,571**	**8,028**	**890**	**4,653**
Regional health care insurance funds	10,368	5,839	762	3,767
Company health care insurance funds	159	75	14	70
Insurance Institution of Austrian Railways and Mining Industry	546	289	25	232
Insurance Institution for Public Servants	1.513	906	40	567
Social Security Institution for Trade and Industry	556	520	19	17
Social Security Institution for Farmers	429	399	30	-

in absolute Source: HV

* general out-patient clinics, out-patient dental clinics, other treatment institutions, out-patient clinics for children and teenagers, institutions for prevention and teenagers, as well as rehabilitation centres and sanatoria

Special health care institutions

In Austria the Insurance Institution for Public Servants is the only competent social insurance agency concerning health and accident insurance for civil servants in federal government, and for most civil servants in federal state government and municipial administration. In addition, there may exist further institutions for health care of civil servants in federal state government and municipical government. Therefore there are 15 other special health (and accident) insurance institutions for civil servants in federal state and municipal government, in addition to the Insurance Institution for Public Servants.

These special health care institutions are no social insurance agencies and are not part of the Main Association of Austrian Social Insurance Institutions and are not subject to surveillance through authorities.

Federal state	Number	Special health care institutions and/or accident insurance institution
Carinthia	1	of civil servants of the city of Villach
Lower Austria	1	of civil servants of the town of Baden
Upper Austria	6	of civil servants of the city of Linz
		of the towns of Upper Austria
		of civil servants of the federal state government of Upper Austria
		of teachers of Upper Austria
		of civil servants of the magistracy of Steyr
		of civil servants of the city of Wels
Salzburg	2	of civil servants of the town of Hallein
		of civil servants of the magistracy of Salzburg
Styria	1	of civil servants of the city of Graz
Tyrol	3	of teachers of Tyrol (on federal state level)
		of civil servants of the federal state government of Tyrol
		of civil servants of the municipal governments of Tyrol
Vienna	1	of civil servants of the city of Vienna
Austria	**15**	

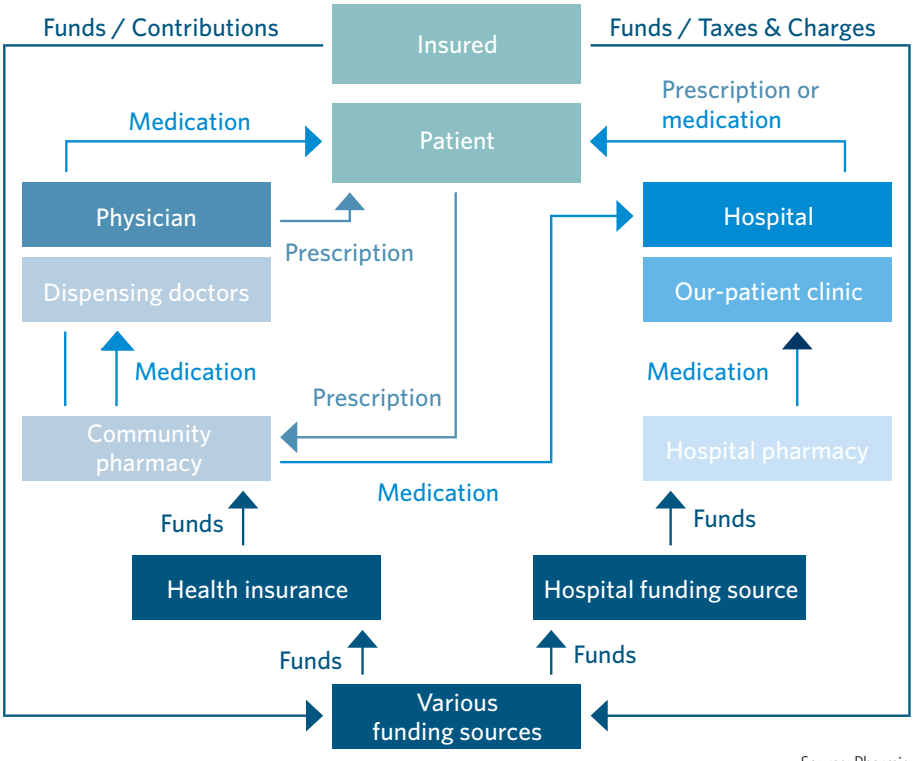
Source: Hofmacher, M.M (2013). Das österreichische Gesundheitssystem. Berlin: Medizinisch Wissenschaftliche Verlagsgesellschaft
§ 2 Officer, Health and Accident Insurance Act (B-KUVG)

1.5 Health Care Structure

Austria has a dense network of medical care institutions. Patients have four different levels of health care providers at their disposal:

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

Structure of Austria's health care system



Source: Pharmig

1.6 Employees in the health care system 2015

As per December 31, 2015, Austria's 8.7 million inhabitants were supplied by 1,340 public pharmacies (with 28 branches), 45 hospital pharmacies and 841 dispensing doctors (who dispense medicines directly to patients).

	Number
Practicing physicians	**48.908**
General practioners	14.275
of whom solely employed physicians	6.360
Medical specialists	23.412
of whom solely employed physicians	11.255
Dentists	4.906
of whom solely employed physicians	594
Physicians in training	6.315
of whom solely employed physicians	6.315
Pharmacy employees	**16.114**
Pharmacists, employed or self-employed	5.647
Qualified staff	6.689
Other employees	3.778
Medical experts in hospitals	**114.903**
Physicians	23.996
Nursing staff	90.907

Source: Statistics Austria, Austrian Chamber of Pharmacists

In total about 180,000 people are employed in the healthcare sector.

1.7 Health care reforms

The public health care system in Austria is one of most cost-intensive in the European Union (see Chapter 1.3). With an over-sized hospital sector (see Chapter 8.1) and insufficiently developed outpatient sector, there are structural imbalances.

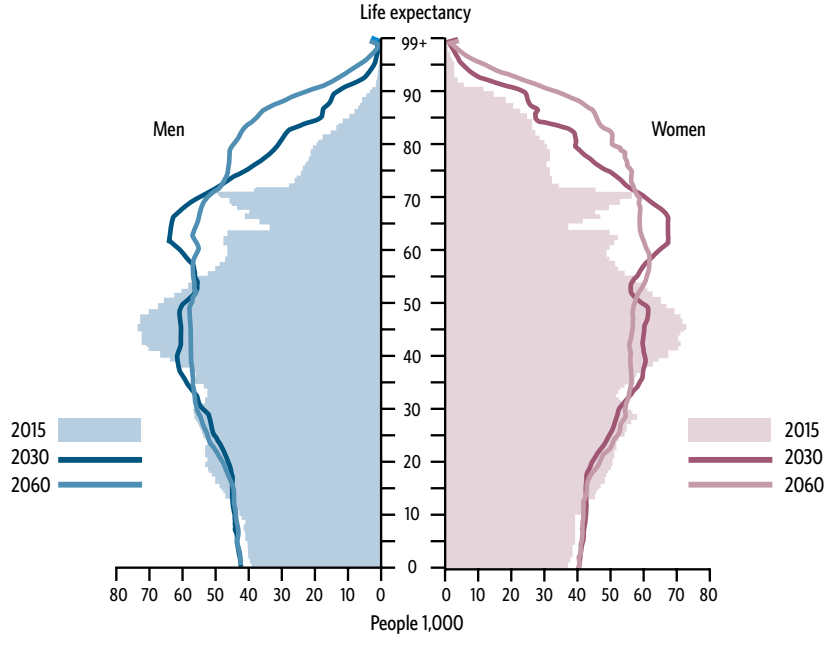
Without making cuts in the system, the Austrian government decided for a basic reform to the cooperation in the health care system. In 2005, a cross-institutional agreement was made on mutual goals in health care (Austrian Health Care Structure Plan). This was followed by programs for the cutting of costs and restructuring of the health insurance institutions starting in 2009 (insurance structural funds) as well as the establishment of a care fund. The health care reform in 2013 should bring about a fundamental change: mutual planning, controlling and financing of the health care system. The required stronger cooperation between federal, states and social insurance was legally determined in a health care reform act. A few changes that were supposed to be implemented through the last health care reform included, for example, the implementation of the electronic patient records ELGA, introduction of e-medication, expansion and strengthening of primary care, limitation of health expenses and much more.

With financial compensation in 2017, new art. 15a agreements were made on the organisation and financing of the health care sector and for target control for health care: the reform efforts should be continued.

2 Population structure and demographic trends

2.1 Population structure

Population pyramid 2015, 2030 and 2060

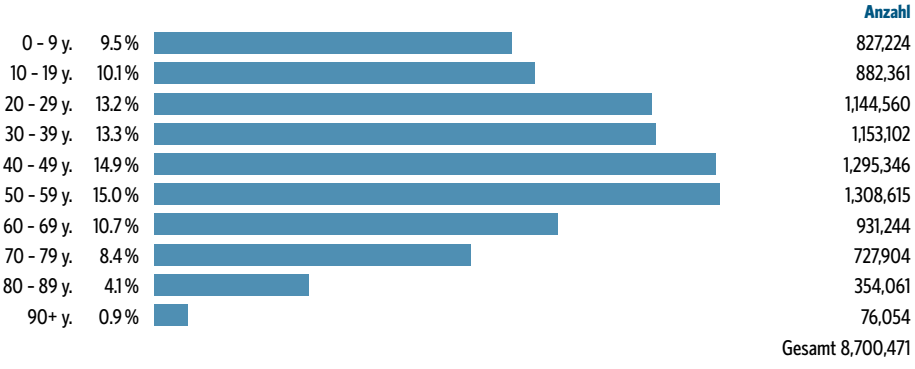


Source: Statistics Austria

Statistics Austria forecasts strong population growth until 2060 and a further shift in the age structure towards higher ages. Since 1995, life expectancy for men has risen by 22 % and that of women by 19 %. This equates to additional 13 years. According to the forecast, Austria is set to have a population of 9.4 million in 2030.

In 2015, there were markedly more women aged 70 and older than men, and this gap continues to grow with increasing age.

Share of age groups in total population in %



Source: Statistics Austria, 2015

In 2015, persons aged over 65 made up 18 % of the total population. According to the forecasts of Statistics Austria, this share is expected to rise to 19 % by 2025 vs. 2015.

2.2 The need for medicinal products by age group

The need for medicinal products in % (national health insurance patients, by no. of packages)

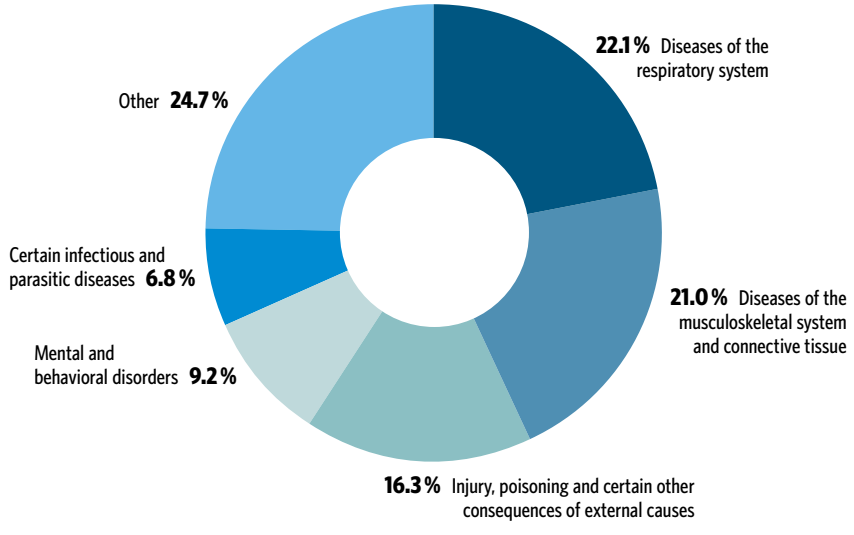
Source: Austrian Chamber of Pharmacists, 2016

There will also be an increase in the need for medicinal products in the course of the demographic transition. The demand for medicinal products increases considerably from the age of 60.

2.3 Frequent causes of illness

Illness groups as percentage of sick leave days

Survey group: blue collar and white collar



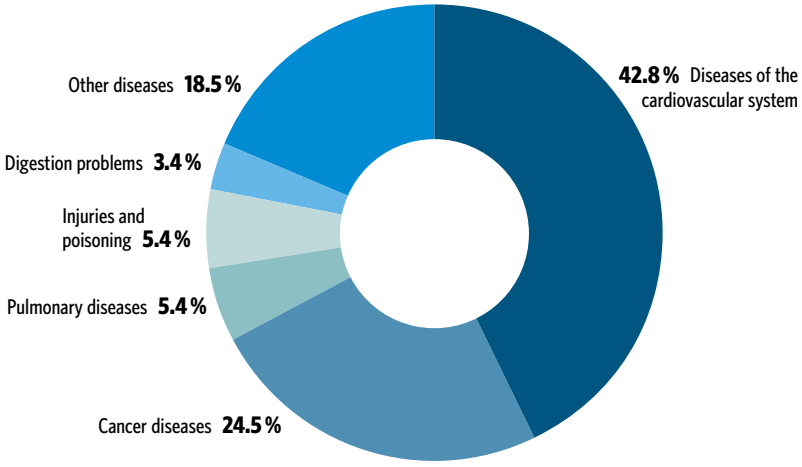
Source: HV, 2015

The 4,055,650 cases of illnesses causing absence from work and the 40,270,601 days of employee absence in 2015 show that illnesses of the respiratory system and of the musculoskeletal system are the main causes for notifications of sickness.

Diseases of the respiratory system together with diseases of the musculoskeletal system represent the cause for approximately 43 % of the notifications of illness.

2.4 Mortality

Mortality by causes of death



Source: Statistics Austria, 2015

Together, cardiac diseases, cardiovascular diseases and cancer cause 7 of 10 deaths.

Considering the growth of the population and its continuous ageing mortality has decreased by 18 % over the past decade. In particular, mortality from cardiovascular diseases has been declining.

Source: Statistics Austria

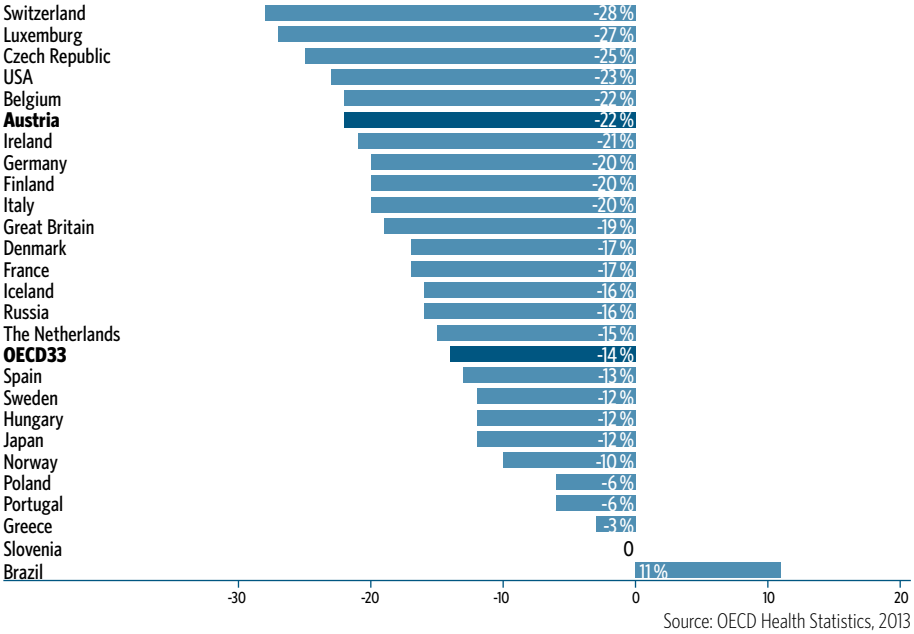
Classification of ICD 10:

- 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.

Cancer mortality overview

IIn 2012 there were 14.1 million new cancer cases worldwide, 8.2 million people died of cancer, and 32.6 million people are living with this disease.
Due to the growth in population and increasing life expectancy, the WHO predicts a further rise in new cancer cases. The three most frequent cancers among men affect the lungs, prostate and bowel, while in women they affect the breast, bowel and cervix.
In Austria, 330,492 people were living with cancer in 2014 (53 % of which were women and 47 % men) – 38,908 people were documented with new cancer cases. This marks a clear increase, compared to 2002 (213,620 people suffering from cancer), which can be attributed to the interaction of the following factors: demographic ageing, a general rise in life expectancy, and the improved survival chances of afflicted persons.
The mortality rate has also decreased significantly: compared to 1990 **cancer mortality in Austria sank by 22 %**. The OECD average shows a decline of 15 %.

Change in cancer mortality, 1990–2011



Source: OECD Health Statistics, 2013

This development can be attributed to the following factors: greater health consciousness, especially with regard to nutrition, a reduction in damaging environmental influences, better medical care and advances in treatment.

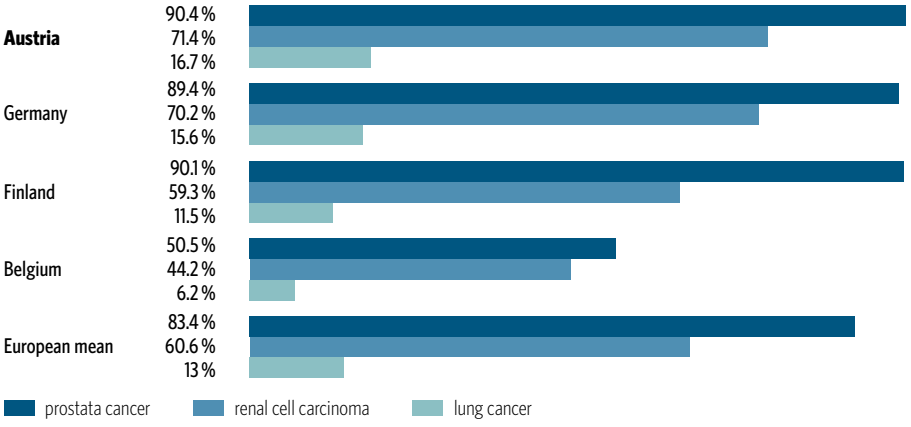
Source: WHO, Globocan International Agency for Research on Cancer, 2012, Statistik Austria Krebserkrankungen, 2016, OECD Health Statistics, 2013

Cancer survival rates

In comparison with other European countries Austria is among the Top 5 countries with regard to 5-year cancer survival rates. With regard to three common types of cancer Austria comes top in Europe: namely lung cancer, prostate cancer, and renal cell carcinoma.

Patients are able to take part in clinical trials early on and therefore gain access to innovative active substances which increase the chances of curing the disease. About a third of all clinical trials are conducted in the field of oncology. Therefore oncology is the field which is most intensively researched into in the Austrian pharmaceutical industry. This means that on frequent occasion cancer patients have access to medication with innovative active substances from an early stage (see Chapter 3.6).

5-year survival rate of certain types of cancer in comparison with other european countries



Source: EUROCARE 5-study "Cancer survival in Europe 1999–2007 by country and age" (Lancelot Oncol. 2014 Jan;15(1):23-34))

3 Pharmaceutical research and development

Research location Austria

According to the "Innovation Union Scoreboard 2016" (IUS) which has been published by the European Commission, Austria is among the group of "Innovation Followers", its research quota of 3.07 % is higher than the EU-28 average of 2.03 %. However, the strategy for research, technology and innovation of the Federal government aims at establishing Austria as an "Innovation Leader" which would require an increase in the research quota to 3.76 % until 2020. Further efforts will be necessary to achieve this aim.

The greatest part of research expenditures (at an amount of € 10.7 billion) within the last 10 years were incurred by companies, taking up 47.1 % on average; on average 36.2 % of spending was provided by the public sector and 16.7 % from abroad. In particular the domestic pharmaceutical industry in Austria contributes to the added value with research commissions. According to Statistics Austria (data from 2008–2010) the innovation activities of the pharmaceutical industry (93 %) are considerably higher in comparison to all other industry sectors (56.5 %). The expenditures for innovations in relation to the total turnover of the companies consist of 14 % in pharmaceutical products vs. 1.7 % in all industry sectors.

In addition to excellent universities, Austria has outstanding and internationally recognised research institutes in the field of Life Science, such as the Research Institute for Molecular Pathology (IMP), the Institute for Molecular Biotechnology (IMBA), or the Research Center for Molecular Medicine (CEMM). 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. Austria is also the location of the European biobanks research infrastructure which is aimed at connecting existing and future biobanks in Europe in order to facilitate access to biological samples for research. In 2014 the Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC), located in Graz, has become operational.

Source: Statistics Austria, Austrian Research and Technology Report 2016

3.1 Active substances

As soon as a new active substance candidate has been identified, it is developed further on a broad scientific basis. In order to ensure continued economic exploitation, a patent is generally taken out for an active substance after it has been identified. The patented active substance then goes through several stages of clinical research.
The following categorisation of active substances is based only on the primary classification of investigational medicinal products in accordance with the EudraCT form used for the submission of clinical trials without further pharmacological differentiation.

Active substances of chemical origin

Chemical substances are natural chemical agents or products obtained through chemical synthesis. Simple chemical medicinal products frequently have a moar mass of no more than 1000 g/mol. They make up the lion's share of the medicinal products approved in recent years.
They include medicinal product groups such as antibiotics, cholesterol-lowering agents (e. g. statins), analgesics (e. g. acetylsalicylic acid) or cytostatics.

- **Generics** (see also Chapter 7.5) are copies of originator products that are offered in the market once the patent of the original expires. They may be approved in pertinent marketing authorisation procedure once a patent or data exclusivity no longer applies for the originator products. Only minor bioequivalence studies are needed to prove the efficacy and safety of conventional generics.

Active substances of biological or biotechnological origin (biopharmaceuticals or biologicals)

Biopharmaceuticals (see also Chapter 7.6) are medicinal products produced in genetically modified organisms using biotechnological procedures. As opposed to traditional chemical active substances, biotechnologically produced active substances are complex, high-molecular and large proteins with a moar mass of several 1000 g/mol, in some cases even up to 500.000 g/mol. Biopharmaceuticals are subdivided into various classes, such as immunomodulators, monoclonal antibodies, enzymes, hormones and vaccines.

- **Biosimilars** are biological medicinal products which are similar to another biological medicinal product ("reference medicinal product") which has already been approved for use. In order to bring a biosimilar on the market, it must be as similar as possible to the reference medicinal product in terms of its quality, safety, and efficacy. Yet also the biosimilar, just like the reference medicinal product, is to a certain extent naturally variable due to the manufacturing process. The active substance of a biosimilar is essentially the same biological substance as the one of the reference medicinal product. Biosimilars can only be similar to the originator product and cannot be identical due to the complex structure of the molecules which are often very large and due to the individual manufacturing process with specific cell lines for each biological medicinal product. Therefore biosimilars are not the same as generic products: Generic products are identical copies of the originator medicinal product which consist of the same active substances to an equal amount.

Biosimilars adhere to the same regulations of EU-legislation which has determined high standards of quality, safety and efficacy. The authorisation procedure for biosimilars involves a multi-stage clinical testing programme which aims to prove that there is no significant difference in the efficacy and safety compared to the originator product. As a rule, biosimilars are approved for the same indications as the reference medicinal product once the patent for the originator product has expired.

For many illnesses biopharmaceuticals provide new treatment opportunities (these include rheumatic diseases, cancer, diabetes, multiple sclerosis, ...). The importance of biopharmaceuticals for the treatment of numerous and, in many cases, life-threatening diseases has increased in previous years. Biosimilars have been in use in the European Union since 2006 in clinical practice.The market share of biosimilars has increased in EU member states and has also increased overall in each product category to different extents depending on market access provisions and pricing mechanisms (see Chapter 7.6).

Foto: iStock/DNY59

3.2 Clinical research

Clinical research means the testing of medication and forms of treatment on people by means of clinical studies. The objective is to prove the effectiveness and tolerability of these forms of treatment and to improve the medical care of future patients. In principle, a distinction is made between clinical trials (intervention studies) and non-interventional studies.

Legal foundations

Every clinical trial in Austria has to be approved by the Federal Office for Safety in Healthcare and needs a positive opinion of the ethics committee. Details on terminological definitions and on the requirements and implementation of clinical trials are set out in the Medicinal Products Act in § 2a and § 28 to § 48.

Within the EU, standardised administrative rules are set out for clinical trials by Regulation 2001/20/EC. However, deviating approaches among different member states in implementing this regulation have led to insufficient harmonisation within the EU. For this reason, the conduction in Europe of multinational clinical trials in particular has proven to be difficult. This should change with the new EU Regulation 536/2014 on clinical trials on medical products for human use, which is due to take effect at the end of 2018. The aim is to standardise and simplify the implementation of clinical trials in Europe by means of a central approval system with standardised applications that will be submitted via a central portal.

Preclinical studies

Before an active substance can be tested in humans, its safety must be proven in cell models (in-vitro tests) and animal models (in-vivo tests). Some tests can be conducted using cell cultures, but most can only be carried out on the entire organism. The animal experiments needed for this purpose are required by law and, in particular, involve pharmacological studies, as well as studies on toxicity, toxicokinetics and pharmacokinetics.
Preclinical studies are often conducted in suitable animal disease models (e. g. knock-out mice) in order to study the effectiveness of an active substance in vivo. Relevant proof of efficacy can not always be provided and is therefore not mandatory. Only when an active substance concluded positively all preclinical tests it can be used in humans for the first time. This marks the beginning of the development stage called clinical trials.

Clinical trials

Thanks to the willingness of many volunteers, new medication can be developed on an ongoing basis, in order to ease the suffering of many patients and provide hope in cases of severe illness. But by participating in a clinical trial, many patients also receive the opportunity to have early access to innovative and in some cases life-saving medicinal products – often many years before these are available on the market. However, each clinical trial also carries a certain risk. Therefore, every person involved does everything possible in order to keep the risks to participants in a clinical trial to an absolute minimum. For this reason, clinical trials for the development of new medicinal products are carried out with the greatest care and under strict conditions. One essential prerequisite of every clinical trial is that participation is always voluntary and may be ended at any time.

The sequence of the individual clinical phases

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 (so-called "first-in-man" studies). Objective: information regarding tolerability, resorption, elimination and any metabolites. Phase I testing is conducted with a limited number (10 to 50) of healthy persons. Healthy trial participants are preferred because the pharmacokinetics of the substance under examination should not be distorted by pathological conditions. However, if the active agent is expected to have any toxic properties (such as substances used for oncological diseases), only persons with the respective disease are included in Phase I trial.

  In order to reduce the risks to the trial participants to a minimum, especially in Phase I trials, a special EU directive was adopted in 2007. It stipulates that every Phase I trial must be based on a thoroughgoing risk analysis, in order to categorise high-risk products and take the necessary measures. It is also essential that a new substance

must not be administered to a number of persons simultaneously. Close diagnostic monitoring must be safeguarded for every single trial participant, and emergency intensive care must be on stand-by at all times.

- **Phase II: Ascertaining the dosage**
  In the next stage, the controlled phase II test, the substance's pharmacodynamic effect is examined. Objective: to ascertain the therapeutic dosage and obtain a biological signal proving the efficacy of the substance. Moreover, the aim is to obtain information regarding tolerability and any interactions. In this phase, the group of trial participant with the relevant illness consists of 50 to 200 patients. The trials are generally controlled, i. e. they include a control group and are double-blind trials (neither physician nor patient know whether the active agent or control is administered). This is intended to prevent any influences on treatment results.

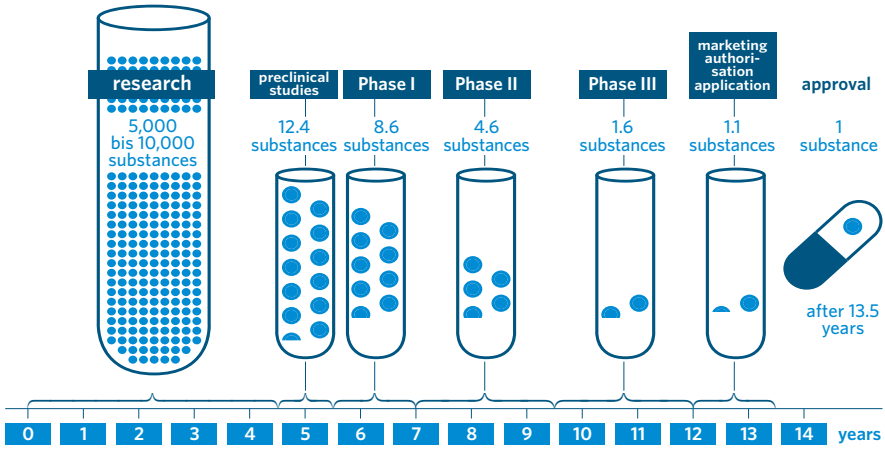
- **Phase III: Establishing the therapeutic efficacy**
  Unlike the previous phases, the test in phase III is carried out on a large group of patients (with the relevant illness). The size of the patient group is determined depending on the indication in order to ensure reliable proof of the effectiveness and to detect any rarely occurring side effects. The duration of treatment of the individual patients in the course of the clinical trial depends on the illness; in the case of chronically progressing disorders, the treatment may even last several years. As a rule, these multi-centre trials are conducted in several countries at the same time (multinational) in order to keep the duration of the overall trial as short as possible. The phase III trials are controlled and double-blind in nature just like the trials in phase II. Once phase III of the clinical trial has been positively concluded, an application can be submitted to the appropriate authorities for authorisation of the medicine.

- **Phase IV: Clinical trial after authorisation**
  In this phase, conducted in the form of a clinical trial, further data is collected after marketing authorisation has been granted. The trials in phase IV are subject to the same conditions as the clinical trials in phases I through III.

Non-interventional study (NIS)

A NIS (e. g. Case-control study, Cross-selectional study, Observational study, Analysis of administrative registers) is the systematic examination of an approved medicinal product administered to patients. The type and duration of the administration correspond to the approved summary of product characteristics and patient information leaflet. Therefore no additional diagnostic, therapeutic or strainful measures may be taken. A NIS is suited for proving the efficacy of a medicinal product in practice and for documenting side effects which have not occured in clinical trials due to limited numbers. Prior to its implementation each NIS has to be reported to the BASG or the Risk Assessment Committee of the Pharmacovigilance (PRAC).

Development phases of a medicinal products



Source: Paul, S.M., et al.: Nature Reviews Drug Discovery 9, 203–214 (2010)

Development costs

According to recent studies, the average cost of developing a new innovative/original medicinal product is up to 2.6 billion US Dollar (DiMasi et al. 2016). 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 trial participants, on the other.

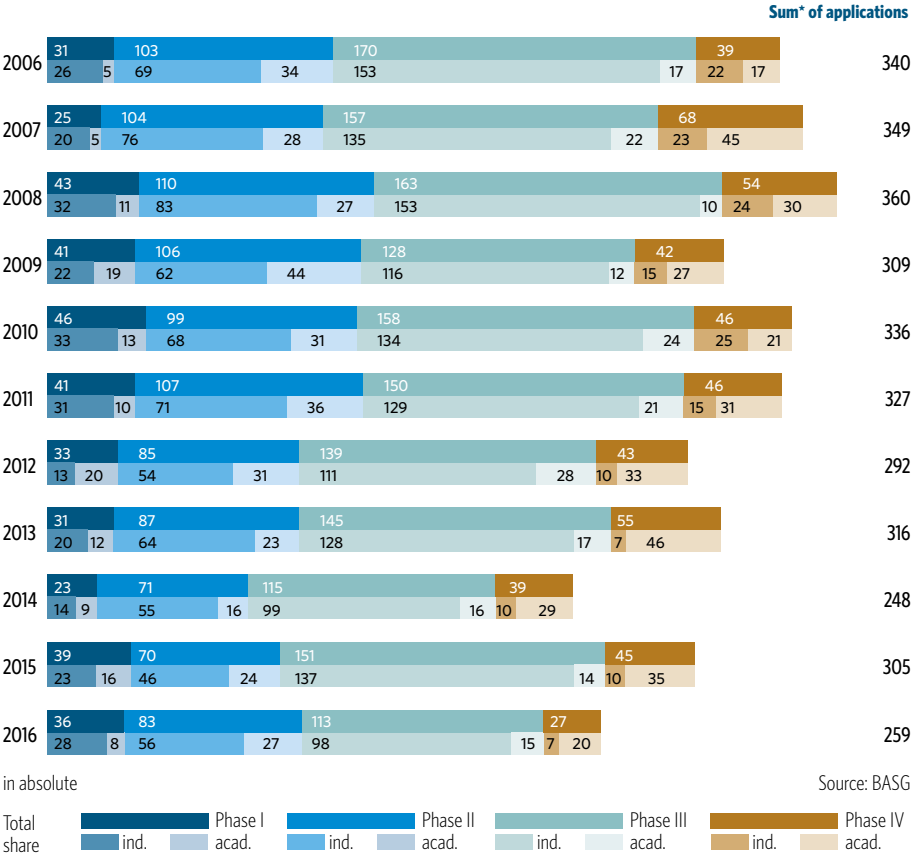
The development of drugs involves high risks: out of 5,000 to 10,000 initial substances, an average of only one single drug is approved in the end. In many cases, it cannot be determined whether active substances are effective enough and whether their side effects are not too onerous until extremely complex multinational phase III studies have been performed. The costs incurred by the many unsuccessful development projects need to be factored in and borne by the companies as well.

Source: EFPIA/PhRMA 2016

Clinical trials in Austria – a statistical overview

In recent years, around 4,400 clinical trials have been applied for annually in the EU/EEA, almost 300 of these in Austria. Overall, applications for clinical trials in Austria have remained constant within the fluctuation range in recent years. There was a clear decline in 2014 and again in 2016.

Distribution of clinical trial applications in Austria according the phases



* Since multi-phase trials (e. g., Phase I/II trials) count twice in this survey, the sum of phases exceeds the indicated sum of applications. The deviations indirectly indicate the number of dual-phase trials.

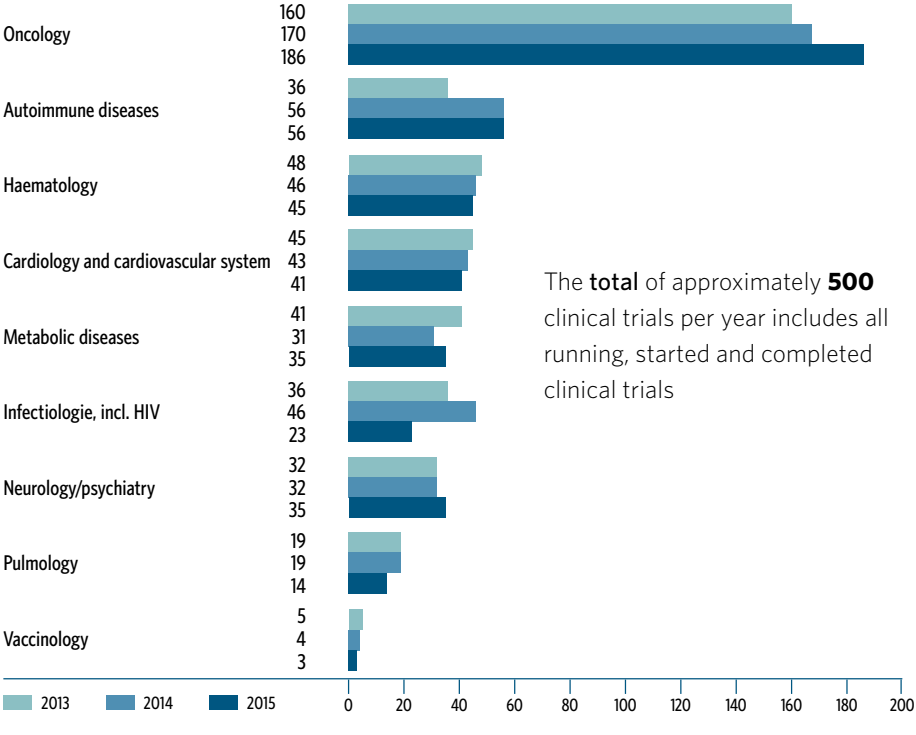
In the EU an average of around 60 percent of clinical trials are carried out by the pharmaceutical industry (industry sponsored), 40 % are implemented by academic researchers (academic sponsored). In Austria this ratio lies at 70 : 30 % as an annual average (two thirds of clinical trials are multinational, one third of trials is conducted in Austria only).

Industry sponsored clinical research in Austria 2015

On many occasions clinical trials run for several years after marketing authorisation has been granted. The numbers of ongoing clinical trials per year (incl. clinical trials which are running, which have been initiated and which have been completed) according to the specified indication areas, as well as the number of patients which actively participate in these trials give us an overview of the services of the pharmaceutical industry.

Pharmig executes an annual survey among the member companies for industry-sponsored clinical research in Austria. Around 35 companies took place in the survey during the past three years retrospectively. This corresponds to a market coverage of approximately 81 % (measured on the sales of all Pharmig member companies).

Ongoing industry sponsored clinical trials according to indication groups



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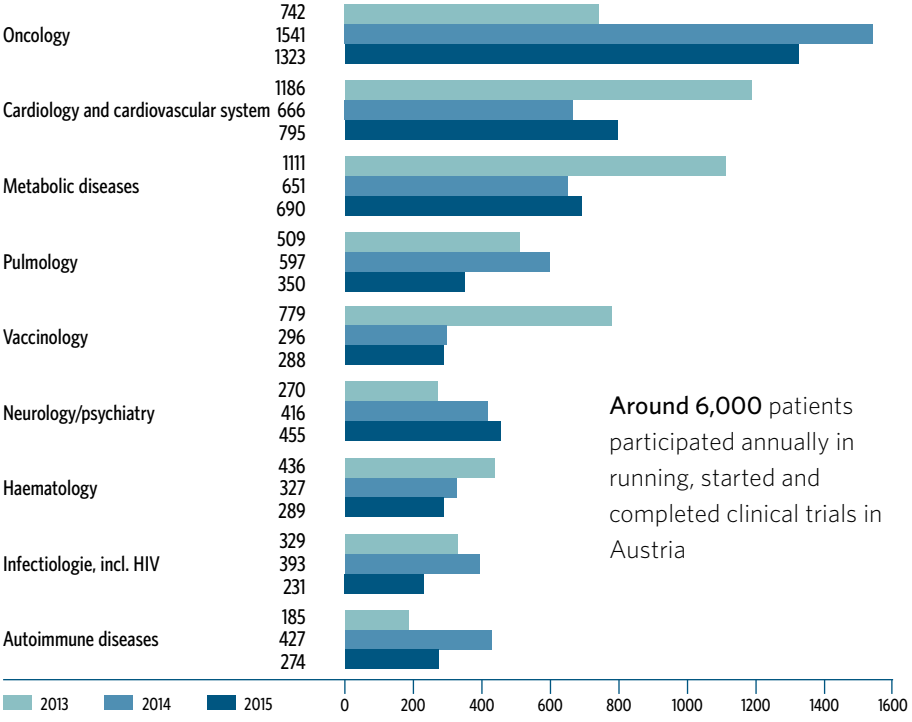
Source: Survey of industry sponsored clinical research in Austria, Pharmig 2013–2015

The number of patients in clinical trials according to the most researched indications

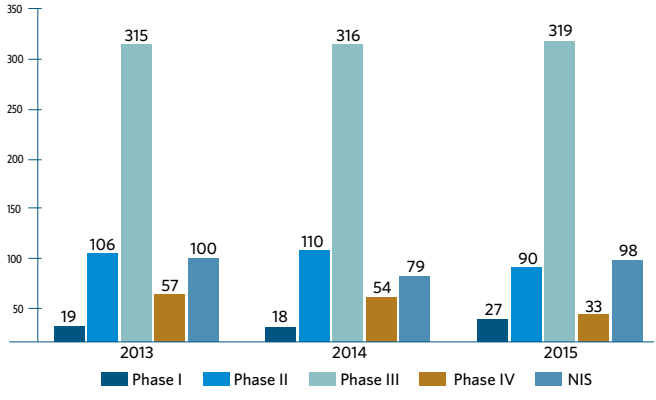


Around 6,000 patients participated annually in running, started and completed clinical trials in Austria

in absolute

Source: Survey on industry-sponsored clinical research in Austria, Pharmig 2013–2015

Number of running clinical trials according to phases and non-interventional studies (NIS)



Total number of clinical trials:

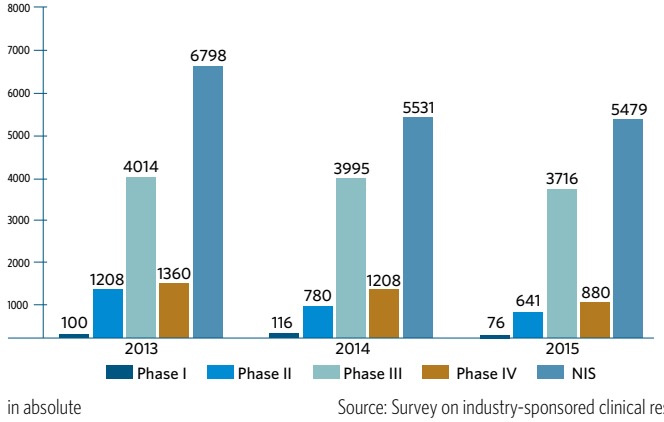
- 2013: 497
- 2014: 498
- 2015: 469

in absolute

Source: Survey on industry-sponsored clinical research in Austria, Pharmig 2013–2015

Furthermore, through the support of the pharmaceutical industry, on average 146 "investigator initiate trials" were made possible per year in the years 2013-2015.

Distribution of patients in running clinical trials according to phases and non-interventional studies (NIS)



Total number of patients in clinical trials:

- 2013: 6.682
- 2014: 6.099
- 2015: 5.313

in absolute

Source: Survey on industry-sponsored clinical research in Austria, Pharmig 2013–2015

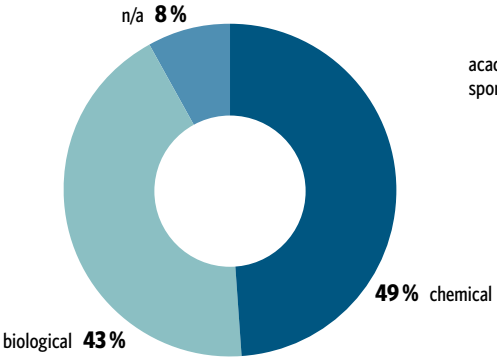
Paediatric pharmaceutical research

50–90 % of medicinal products conventionally used in paediatrics are not authorised for children because paediatric trials were considered unethical until recently. However, a suffi cient supply of children with medicinal products which have been adequately studied and authorized for use in children, is essential and has therefore been required by EU regulation since 2007.
All new marketing authorizations, changes in the indication, form of administration or composition of the medicinal product must be implemented within the framework of a development plan (Paediatric Investigation Plan (PIP). Clinical trials involving children and adolescents are essential for this purpose.

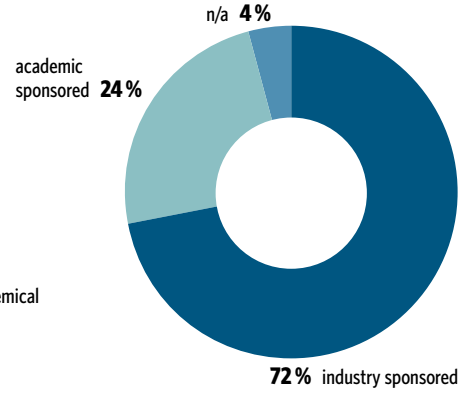
Evaluation of pharmaceutical trials involving children and young people in austria, analysis according to austrian agency for health and food safety, data for the years 2007–2011

- Number of clinical trials registered in Austria within the period 2007–2011: 134*
- Top areas of specialisation: Haematology/oncology, pulmonology/allergology, neurology
- Majority of these trials (72 %) were sponsored by industry
- With approx. every 2nd study an instance of market approval was already in place
- 43 % of the active substances were biopharmaceuticals
- In 18 % of the studies rare diseases are under investigation

Type of substance



Type of financing



* In comparison: in Germany in the period from 2007–2011 approx. 750 clinical trials took place involving children and young people (source: vfa 2011)

OKIDS – Child research network

OKIDS is a public-private partnership acting as a network for promoting pediatric studies in Austria (www.okids-net.at). It serves as a central contact point for sponsors of all important stakeholders in pediatric research (pharm. ind., university medical centers, coordination centers for clinical studies, specialty departments, etc.).
Together with the Federal Ministry of Health and funding from the "joint health care objectives from the pharmaceutical framework contract", the following 30 companies have been supporting OKIDS since 2013 with 5-year start-up funding:

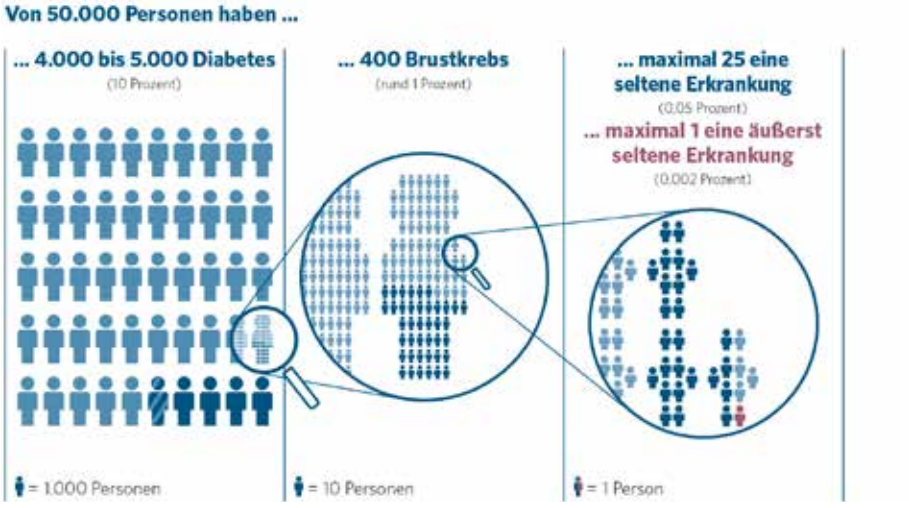
Since its foundation in May 2013, OKIDS has participated in 95 industry-sponsored AMG studies at the 5 OKIDS locations. In all, OKIDS received 26 applications for pharmaceutical studies with children and adolescents in 24 different paediatric indications (as of end of 2016).
In addition, at its first attempt OKIDS managed to fulfil all of the criteria to be adopted successfully into the best of four categories of the European Network of Paediatric Research at the European Medicines Agency (ENPR-EMA), thus achieving international visibility. http://enprema.ema.europa.eu/enprema/showall.php

Pharmaceutical research of rare diseases

Rare diseases are disorders which are life-threatening or chronically debilitating and which affect less than 5 in 10,000 people (in relation to the European average). Of around 30,000 diseases known to this day, 6,000 to 8,000 count as rare diseases and 50 % of these affect children. In Austria about 400,000 people (i. e. 6–8 % of the population) suffer of rare diseases; within the EU the estimated number of affected people amounts to 30 million.

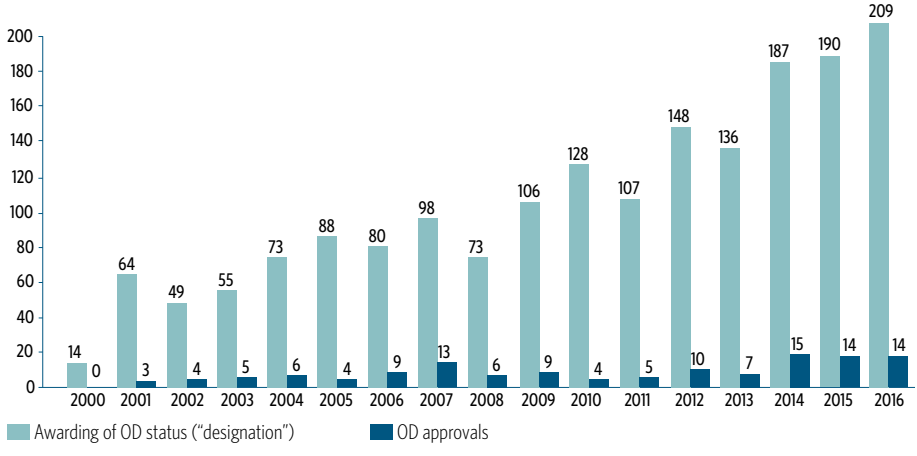
The European regulation concerning medicinal products for rare diseases (EC) No. 141/2000 has been set down in 2000 in order to promote research and development of medicinal products for rare diseases (so-called orphan drugs) in pharmaceutical companies.Through this regulation the companies are offered with reduced costs of marketing authorisation, as well as exclusive marketing rights for ten years. The orphan drug status must be requested from EMA at any point during the development of such medicinal product before applying for marketing authorisation.The examination of the authorisation application, in the same manner as with other medicinal products, takes place via the centralised procedure of the Committee of Medicinal Products for Human Use.

What is rarely? A comparison:



2,715 applications for orphan drug status have been filed from 2000 to 2016. In 1,805 cases orphan drug status has been awarded but, so far, only in 142 of these cases marketing authorisation has been granted. The great number of applications (2,715) reflects the high level of research work done in this area and it shows that the inducements offered by the regulation are received by the companies. However, the low success rate (142) demonstrates the high entrepreneurial risks for the companies.

Awarding of orphan drug status vs. approval of orphan drugs (2000–2016)



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Source: Committee for Orphan Medicinal Products (COMP) meeting report on the review of applications for orphan designation, January 2017

The national action plan for rare diseases (NAP.se)

The NAP.se was published at the end of February 2015 with the objective of improving the life situation of all affected patients and their relatives. It was commissioned by the BMGF and written by the NKSE (National Coordination Office for Rare Diseases).

The starting point for the plan was driven by European requirements (e. g. recommendations and guidelines), the national needs survey "Rare Diseases in Austria" (Voigtländer et al 2012), structured exchanges with national experts and current national points of reference such as the framework healthcare objective, the healthcare reform or the children and youth healthcare strategy.

The NAP.se combines plan and strategy, and defines new key thematic focuses that take consideration of both European recommendations and national requirements. A central element is the establishment of centres of expertise and their networking in order to combine knowledge and provide patients with rare diseases with faster and better diagnoses as well as the best possible therapy options. The research and development of new medical products, with the help of networked and combined expertise, is particularly important in the case of rare diseases. It is essential that patient care can continue to be provided near to the home.

The NAP.se and information about the NKSE can be found under the following link:
http://www.bmgf.gv.at/home/Schwerpunkte/Krankheiten/Seltene_Erkrankungen_in_Oesterreich
http://www.goeg.at/de/Bereich/Koordinationsstelle-NKSE.html

Transparency of study data

- The U.S. National Institutes of Health keep the largest public register since 1997. They publish study data from all 50 federal US states and from a further 180 countries:
  https://www.clinicaltrials.gov
- The European Clinical Trials Register (EudraCT) by the European Medicines Agency (EMA) has made study data from the EU, Iceland, Liechtenstein and Norway publicly accessible since 2011. As of 21 July 2014 also the evaluation report of clinical trials II-IV must be published by the sponsoring party. This must also be carried out retroactively for all trials which have been conducted on the basis of Regulation 2001/20/EC until July 2016 at the latest:
  https://www.clinicaltrialsregister.eu/
- Non-Interventional Studies which have been commissioned by authorities and which are conducted in several EU member states, so-called PASS (Post Authorisation Safety Studies), must be reported to he EU PASS register of EMA:
  http://www.encepp.eu/
- As of 1 January 2015 full access to clinical trial data in the centralised approval procedure of EMA will be possible, based on the "EMA policy 0070 on publication of clinical data". Upon completion of the first implementation phase, interested partied can access clinical reports by means of a registration process on the EMA website:
  http://www.ema.europa.eu/ema/ (Human Regulatory Faculty / Clinical data publication)
- Many companies have voluntarily committed to support the responsible use of clinical trial data and also enable full access to their study data. You can find a compilation of these companies and links to their respective portals in the EFPIA Clinical Trial Data Portal Gateway:
  http://transparency.efpia.eu/responsible-data-sharing/efpia-clinical-trial-data-portal-gateway
- In the NIS register of the medical market supervision of AGES (Austrian Agency for Health and Food Safety) you can find information on all NIS which have been reported in Austria:
  https://forms.ages.at/nis/listNis.do

3.3 Production and quality assurance

Scope of Pharmaceutical Production

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.

GMP – The basic rules of manufacture

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

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
- Valdiations
- Quality Control
- Complaints and recall

National and international regulations

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 mainly by the Medicinal Product Site Regulations (german: „Arzneimittelbetriebsordnung", AMBO).

Monitoring of the regulations is conducted by the health authorities of the respective countries. The Austrian Federal Office for Safety in Healthcare (BASG) is the responsible enforcement authority for Austria together with the Austrian Medicines and Medical Devices Agency (Medizinmarkaufsicht) from the Austrian Agency for Health and Food Safety (AGES).

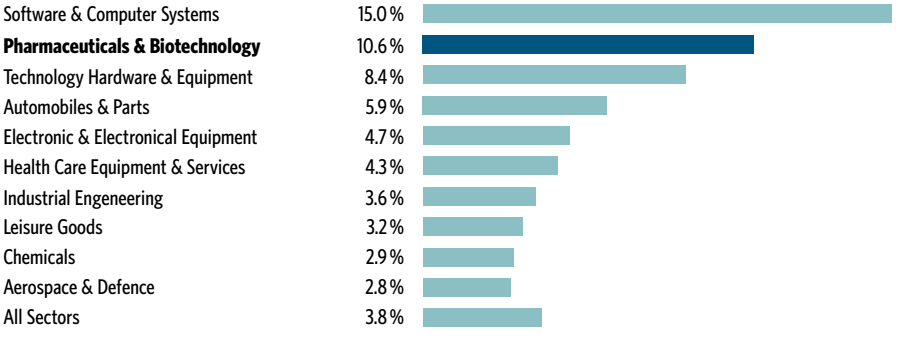
Measures against falsified medication

The revision of the European medicinal products directive of July 2011 "to prevent the entry of falsified medicinal products into the legal supply chain" presented the pharmaceutical industry with numerous changes. By the beginning of 2013 the GMP requirements for active pharmaceutical ingredients were tightened and new rules took effect as of mid-2013 with regard to the import of active ingredients from non-EU countries. In addition, as of mid-March 2016, manufacturers must conduct a risk analysis for all excipients used, to determine the appropriate GMP.
However the greatest change based on this directive will not be implemented until the beginning of 2019: new safety features on all pharmaceutical packaging should make any manipulation of the packaging immediately identifiable and safeguard the traceability of the medication from the manufacturer to the pharmacy. The specific legal requirements at EU-level were published in February 2016.

see also Chapter 5.2

3.4 Research and development – investments

Researchrate, by sectors (Europe)



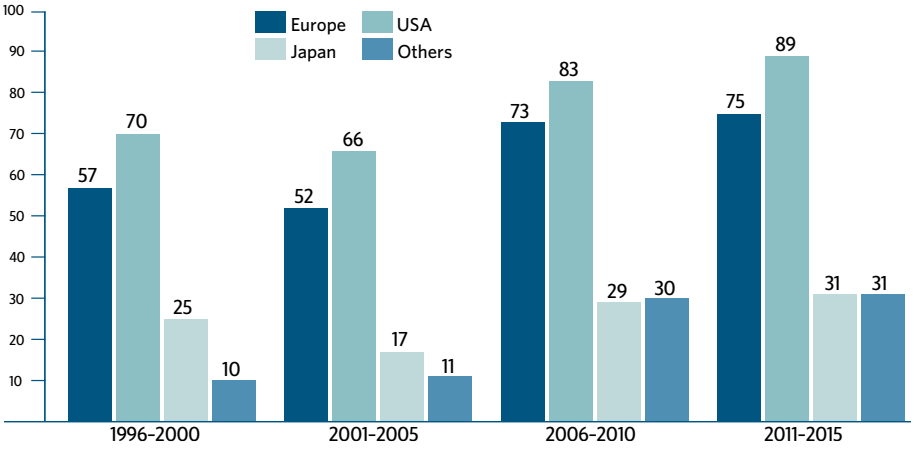
Source: The 2016 EU Industrial R&D Investment Scoreboard

The sector of the pharmaceutical and biotechnological industries is still in 2nd place in the area of Research & Development in the EU: 14.4 % of sales were invested in R & D in 2014.

The R&D intensity (= investments in R&D relative to sales) of the pharmaceutical and biotechnological industry is far higher than in other industries, such as the software, hardware, electronics, leisure goods, automobile, aerospace and defence industries, etc. It is above the EU industry average of 3.4 %.

3.5 Medicinal product innovations

New molecular entities by region



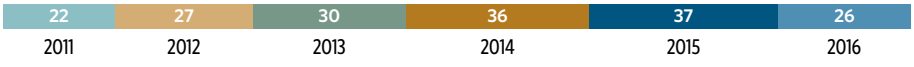
in absolute

Source: SCRIP/EFPIA, 2016

- In 2016, 82 new medicinal products for human use were approved in Europe (EMA)
- 27 of these contain a new active substance
- The recently approved medicinal products treat cancer, infectious diseases, cardiovascular and inflammatory diseases of the skin, type 2 diabetes, etc.
- In 2017, countless new medications are expected for the treatment of cancer and auto-immune diseases as well as for the treatment of patients with rare diseases (with significant metabolic disorders or muscle diseases).

Source: European Commission, VFA

Number of innovations in Austria



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Source: IMS DPMÖ, 2016

From 2011 through 2016, a total of **178 new products** were launched on the market in Austria.* In 2016, innovations achieved a **share of sales of 12 %** on the total pharmacy market.

* New molecules; products not sold in pharmacies not included.

Timeline of pharmaceutical developments

1848	Chloroform used as an anaesthetic in surgery
1891	First drug against diptheria, an infection of the respiratory tract that is usually lethal with children: diphtherpia 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
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
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
1987	First preparation against HIV / AIDS
1993	First drug to 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 two new active principles against HIV infection
2009	First trifunctional antibody; for the treatment of ascites in patients with EpCAM-positive tumours
2011	Extending the life of patients suffering from melanoma by administering a drug with new mode of action
2011	High chances of recovery in difficult Hepatitis C (subtype 1 viruses) cases through new antiviral drugs (in combination with PEG-alpha interferon and an older antiviral drug)
2011/12	Enhanced life expectancy with metastatic black skin cancer (melanoma) with medications with new active principles
2012	First gene therapy with approval in industrial nations, for the relief of pancreatitis in patients with a deficiency of the lipid metabolism (LPLD)
2013	First vaccine against meningitis caused by meningococcal serogroup B
2013/14	Medications cure multiresistent tuberculosis with three active principles
2013/14	The chances of curing Hepatitis C over 90 % due to new antiviral drugs in combination with other medications
2015	Medication lowers the mortality of patients with chronic heart failure
2015	Medications, so-called PCSK-9-inhibitors, significantly lower the cholesterol level for patients with an extremely high cholesterol level

Source: VFA, excerpt – timeline of pharmaceutical developments

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

3.6 Achievements of innovative therapies

Medicinal products provide an important contribution to our society: they help heal, relieve or protect against diseases. Medicinal products help in multiple ways: they relieve the patients of pain and stress and save the health care system and economy costs by reducing the days of sick leave, shortening or avoiding stays in hospitals (replacement for operations). That is why medicinal products and medical progress provide a significant contribution to a longer life.

The following examples show how innovations in the development of medicinal products can change the entire health care system and what chances they offer – above all saving lives and giving people with diseases more quality of life again.

HIV/AIDS

The once fatal infection of HIV became a chronic disease through innovative medicinal products: the mortality rate decreased significantly. Thanks to this development, those infected with HIV can live a mostly normal life and also have a much higher life expectancy than twenty years ago. With the first treatment possibilities, affected individuals still had to take countless pills and the stress caused by side effects was comparably high. In the meantime, there are antiretroviral therapies where the patient only has to take one pill a day.
Around 12,300 people in Austria live with diagnosed HIV, of which 447 were infected in 2016.

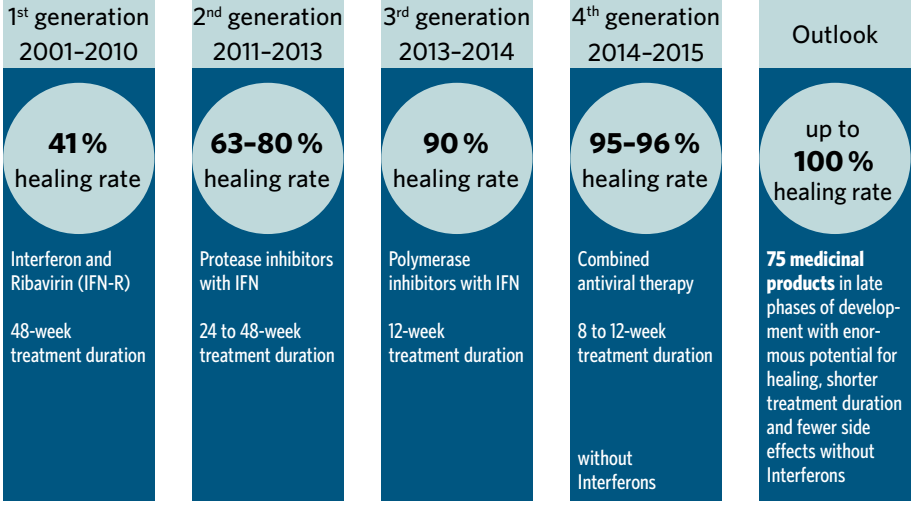
Important milestones in the treatment of HIV:

Now there are more than 35 medications available as individual active substances or fixed combinations of up to 4 active substances for HIV therapy.

Source: Aidshilfen Steiermark, Austria, Germany

Hepatitis C

Due to the often-inconspicuous signs of the disease, hepatitis c patients often do not notice their disease in the beginning. An infection with the hepatitis C virus (HCG) lasting more than six months is identified as a chronic HCV infection. While the only treatment option in the past was a liver transplant in the event of an advanced disease or inefficient treatment, there is now great progress in the therapy thanks to innovative medicinal products: shortened treatment duration (12–72 weeks), high healing rates (no viral load can be traced in the blood any more for more than 90 % of the treated patients), clearly less side effects, no more transplants in an advanced stage.
A chronic disease has become an infection that can be eliminated. This shows that the discussion about costs of innovative medicinal products should never disregard the benefits for the patients and the society.



Source. BPI Pharmadaten 2016

Cancer

Modern treatments of cancer within the last 10 years have helped patients to increase quality of life and gain valuable time of life. Cancer is increasingly turning into a chronic illness and can now often be healed in some areas and is easier and easier to treat with new diagnostic and therapeutic possibilities (see Chapter 2.4). Furthermore, affected individuals can now participate actively in life longer. The mortality-related loss of productivity has decreased throughout Europe by approximately 13 %. Medical progress was achieved over the past years in the treatment of breast, skin and lung cancer.

Cancer research and treatment is very different and complex. Now there are more than 250 types of cancer. Factors like form, structure, genetic modifications and molecular properties influence the growth of the tumour.

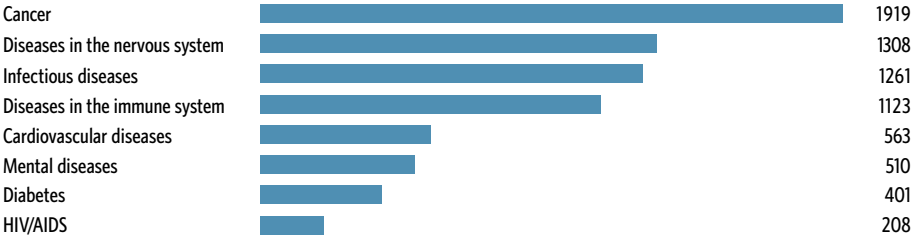
More than 98 new active substances were approved in Europe over the past 20 years for oncology. Countless other medications are currently being developed: oncology accounts for approximately 31 % of the registered biopharmaceutical active substances.

The use of monoclonal antibodies has also proven itself in therapy and diagnostics. The usage of active substances should support the immune system in detecting and killing off cancer cells.

The treatment of cancer diseases accounts for approximately 6.5 % of the total health expenses in Austria. This corresponds with the European trend, which has remained constant at around 6 % over the past 20 years. The cost-intensive hospital sector accounts for nearly 50 % of the expenses. Due to the new therapies, an increasing number of patients can receive outpatient treatment.

Source: IHE Comparator Report 2016, EMA, IMS, Pharmig Factsheet Onkologie 2016

Currently more than 7,000 medications are being developed throughout the world:



Source: IFPMA Facts & Figures 2017

3.7 Patent Law

Research and development are investments in medical progress. Furthermore, this is also an investment in the future of the company: future profits do not only guarantee competitiveness and growth, but rather jobs as well. The development of a medicinal product normally takes more than 10 years (see Chapter 3.2). Due to the long-term commitment of capital, patent protection is one of the most important basic conditions.

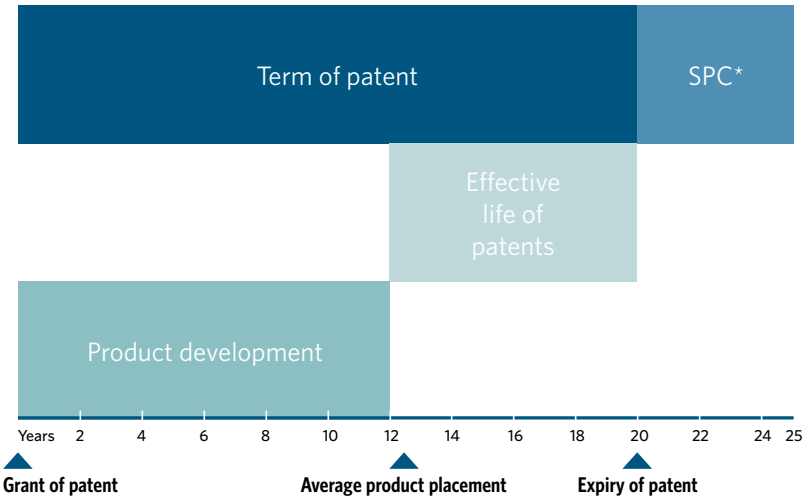
Patents have two primary functions:

- Inventions are made accessible to the public through publication.
- The economic usage is protected against imitation for a legally defined period of time (in favour of the patent holder, who finances and executes the research and development).

With the patent-holder's consent, other manufacturers can use the patent as well (subject to license fees). Patents also guarantee that there will not be an absolute monopoly. The patent law does give the inventor a limited protection against imitation, however, the patent-holder still has to have their products and procedures prove themselves against other competitors: patent-protected medicinal products compete with medicinal products that are already on the market as well as other innovative medicinal products in the affected indications. A patent does not even illustrate the allowance to use the invention: the usage right is regulated through other laws, like the Medicinal Products Act. Patented medicinal products also have to run through regular approval procedures before they can be brought on the market.

The protective effect of the patent is the best incentive for investments in the area of research and development.

Duration of patent protection



* supplementary protection certificate max. 5 years

Source: Pharmig

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. 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.

On average, effective patent protection is provided for a period of 8 years.

After expiration of the patent protection, other companies may produce and sell medicinal products with the same active substance (generics) or with similar active substances (biosimilars) - see chapter 3.1. After expiration of the patent, original medications can therefore no longer provide a contribution to refinancing research and development cost.

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, patentprotected 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**

  Companies can apply for an orphan drug status at the European Medicines Agency (EMA) for the development of medicinal products for rare diseases. Certain criteria determined in the EU order on medicinal products for rare diseases no. 141/2000 must be fulfilled for this purpose. An orphan drug receives ten-year market exclusivity with the approval. This means other orphan drugs for the same rare diseases can only be permitted during these 10 years if they are either more effective or more tolerable or to overcome a supply bottleneck. This offers the approval holder a relative guarantee that they can exclusively sell their medicinal product in a small market for a limited amount of time.

4 Marketing authorisation for medicinal products

4.1 Procedures

Medicinal products may only be placed on the market 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 and 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 exclusively for Austria. The Austrian Medicines and Medical Devices Agency evaluates the application while the Federal Office 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 by 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 authorised. 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.

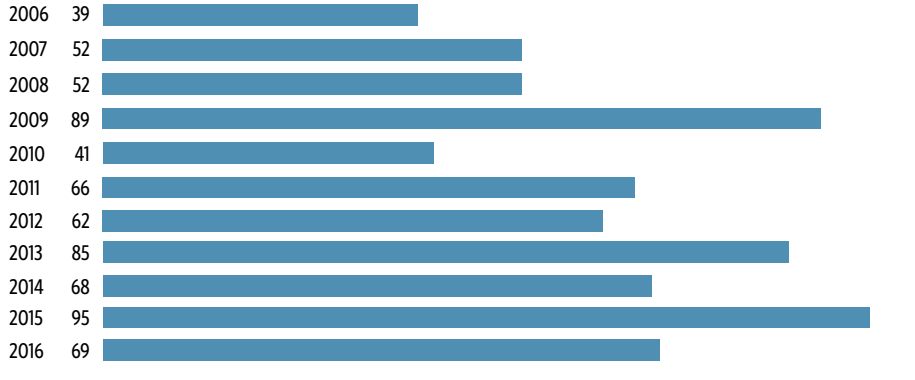
- **Centralised procedure (EU)**
  A centralised procedure has been in place since 1995, at the completion of which a European Authorisation is awarded. In a centralised procedure, the authorisation is

granted by the EU Commission and is valid in all EU Member States. Authorisation through this procedure is mandatory for biotechnical medicinal products, medicinal products for advanced therapies, certain veterinary drugs, orphan drugs as well as new substances for the following therapeutical indications:

- acquired immunity deficiency syndrome
- cancer
- neurodegenerative diseases
- diabetes
- auto-immune diseases and other immune dysfunctions
- 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.

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 regulation concerning the centralised procedure has taken effect in November 2005, only one compulsory centralised procedure remains applicable for certain medicinal products.



Source: European Commission (per 10.02.2017)

4.2 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 can revert to the available data of the original preparation. One therefore speaks of a "referring authorisation". This exemption markedly decreases the term for the approval 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)
- Labelling of the outer packaging
- Prescription status (information on whether the medication requires a prescription or not)
- Distribution channel (e. g. to be sold only at pharmacies, required refrigerated transport, etc.)

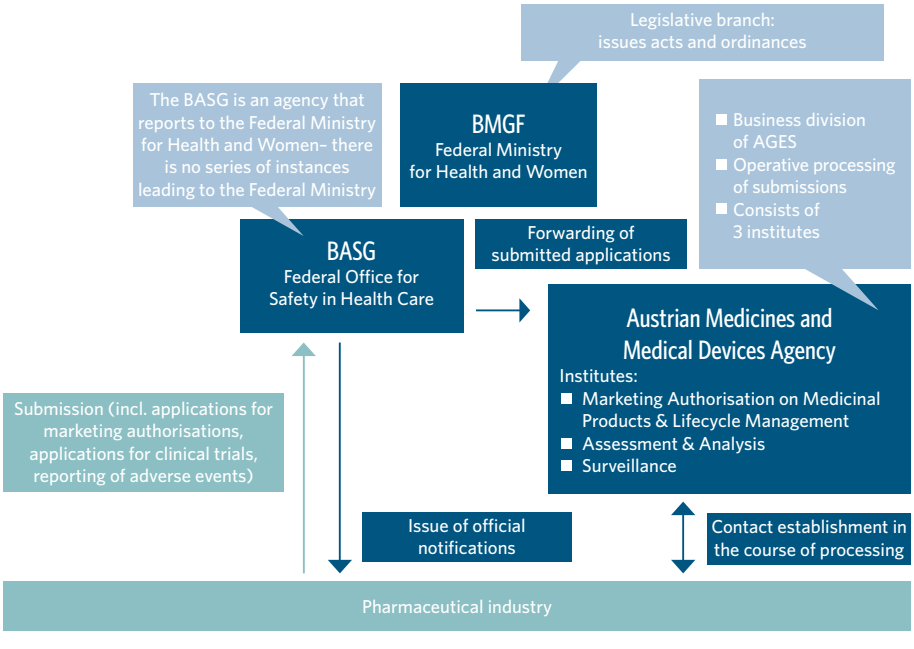
When a pharmaceutical is approved according to the MPA, it is designated as a medicinal product.

Competent authorities in Austria

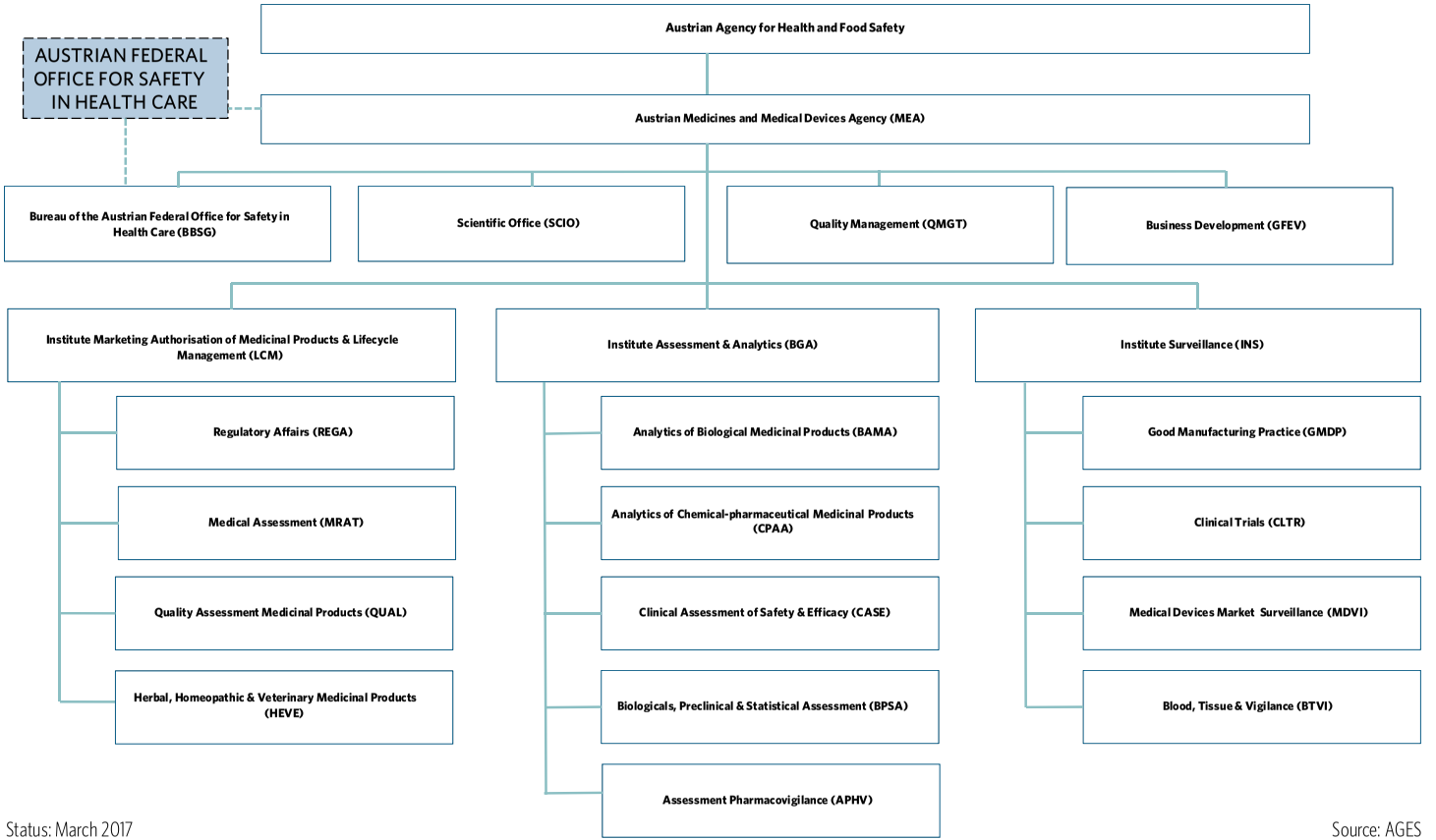
Until the end of 2005, marketing authorisations for medicinal products were granted by the Federal Ministry for Health and Women– starting in January 2006, the Federal Office for Safety in Health Care (BASG) took on this sovereign responsibility. The operative performance of the pharmaceutical and medicinal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

The Austrian Medicines and Medical Devices Agency ist one of the 6 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 Office for Safety in Health Care was set up to support the Austrian Medicines and Medical Devices Agency. The Federal Office for Safety in Health Care (BASG) is a federal office responsible for the implementation of state-conferred responsibility (e. g. issue of notification). The operational level is represented by the Austrian Medicines and Medical Devices Agency with its 3 institutes (status: 2014).

Drug regulatory affairs were moved to the Austrian Medicines and Medical Devices Agency of AGES to achieve, among other things, faster processing of applications with the goal of more rapid access to pharmaceuticals.



Austrian medicines and medical devices agency of AGES – organisational chart



Status: March 2017

Source: AGES

4.3 Number of medicinal products

Total number of approved medicinal products for human use 2015

Approved medicinal products for human use	9,108
Allergen manufacturing procedure	63
Biological medicinal products	350
Homeopathic medicinal products	639
Medicinal gases	31
Herbal medicinal products	210
Radioactive pharmaceuticals	42
Chemical medicinal products	7,759
Medicinal products that represent a monography of the ÖAB/Ph.Eur*	14

* § 9c Medicinal Products Act

Source: Austrian Medicines and Medical devices Agency

Number of registered medicinal products for human use 2015

Registered medicinal products for human use	4,267
Pharmacy-proprietary medicinal products	722
Homeopathic medicinal products	3,357
Traditional use registration for herbal medicinal product application	188

Source: Austrian Medicines and Medical devices Agency

4.4 Prescription status (human medicinal products)

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.

Prescription medicinal products
Non-prescription medicinal products (OTC)

Source: Austrian Medicines and Medical devices Agency

Around 32 % of the medicinal products for human use approved in Austria are available as non-prescription medicinal products in pharmacies.

5 Pharmacovigilance

Pharmacovigilance is the science of, including the activities related to, the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem, e. g. abuse, misuse and quality defects.

Underlying objectives of the applicable EU legislation for pharmacovigilance are:

- preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure; and
- promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public.

Pharmacovigilance is therefore an activity contributing to the protection of patients and public health.

Pharmacovigilance system

The Pharmacovigilance system is used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Title IX of Directive 2001/83/EC. It is designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance, i. e. the evaluation of the positive therapeutic effects in relation to the risks relating to the quality, safety or efficacy of the medicinal product.

5.1 Pharmacovigilance after approval

The European regulatory authorities decide on the approval of medicinal products after they have assessed the results of laboratory tests and clinical trials. Only those medicinal products whose benefits are proven to outweigh their risks reach the market. This guarantees that patients have access to the treatment they need, without being exposed to inacceptable adverse effects. In general, a limited number of patients participate in clinical trials for a defined period under controlled conditions.
Under real conditions, a larger and more heterogeneous group of patients will use the medicinal product. They may suffer from various different illnesses, and may also take other medicinal products.
Some less frequent adverse effects may occur only when a large number of persons use a medicinal product over a long period of time.

It is therefore essential that all medicinal products placed on the market must continue to be monitored for safety. Since the beginning of 2011, the additionally monitored medicinal products include newly authorised drugs as well as those for which the regulatory authorities require further studies, e. g. on long-term use or rare adverse effects that were observed during clinical trials.

The black triangle

The European Union has introduced a new label for medicinal products, which will be monitored especially closely. On their package insert, these medicinal products shall carry a black triangle, standing on its apex, together with the following brief sentence:

▼ "This medicinal product is subject to additional monitoring".

All medicinal products are monitored carefully after their introduction to the EU market. Medicinal products labelled with the black triangle shall be monitored even more closely. This can occur if there is less information available than for other medicinal products, for example because it is a new product on the market. It does not mean that the medicinal product is unsafe.

Costs of pharmacovigilance

The industry has to make considerable efforts in order to meet legal obligations regarding pharmacovigilance. These include the installation of their own pharmacovigilance systems, the reporting of suspected adverse reactions, literature research, signal detection, and the compiling of periodic safety update reports (PSURs). In addition, there must be an ongoing technical connection and provision of information to official databases.

Amendments to the European pharmacovigilance laws in 2012 brought an increasing shift in administrative tasks in the area of drug monitoring from the member states to the European Medicines Agency (EMA). This was accompanied by a large increase in fees. As well as an annual fee for the maintenance of the EMA IT systems, additional five- to six-figure procedure-based fees are charged for PSURs, post-authorisation safety studies and pharmacovigilance-related referrals.

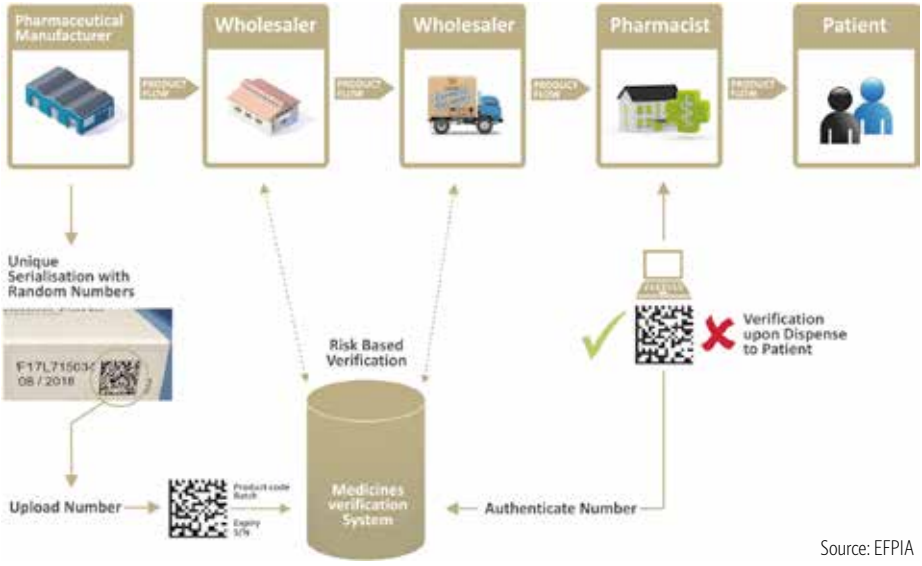
It is estimated that an average pharmaceutical company with a wide range of active ingredients could pay up to 20 million Euro annually in pharmacovigilance fees alone.* Since the monitoring of the medicinal products market is part of the general tasks of the EMA and national authorities to ensure public health, the European pharmaceutical associations believe that these authorities should be financed in part by the European Community, as is also stipulated in EU medicinal products legislation.

* Source: http://www.biopharminternational.com/extending-scope-pharmacovigilance-comes-price

5.2 Measures for Protection against Falsified Medication

Coding and serialisation of medicinal products

The detailed legal requirements concerning the traceability of medicinal product packaging are defined at EU-level with the delegated regulation on "detailed rules for the safety features appearing on the packaging of medicinal products for human use", which was published in the official journal of the EU in February 2016. There will now be a transitional period of three years, after which the regulation shall be applied from 9 February 2019.



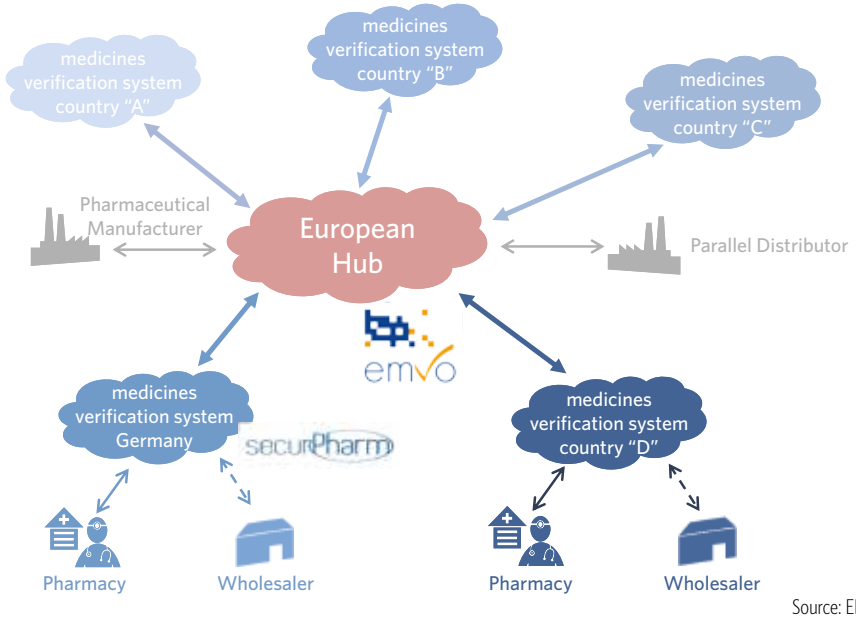
Source: EFPIA

In principle this affects all prescription drugs for human use, exceptions can be found on the "Black & White List" of the regulation. In future, all medicinal product packaging will be fitted with a one-off, randomised serial number, which will be encrypted in a two-dimensional barcode, together with the batch number and expiry date. This shall be applied to the packaging by the pharmaceutical industry and entered into a database. While wholesalers must check the code only in certain, defined cases (e. g. when buying from another wholesaler or in the case of returned goods), the mandatory checking and deactivation of the serial number must be carried out directly when issuing to the patient (mainly in the pharmacy). When repackaging, parallel traders must replace the safety features with equivalent features and create a link to the original package data. A deactivated serial number means that the package has already been issued. If the name serial number reappears at a later time, this indicates a suspicion of falsification.

The European system of serialising medicinal products

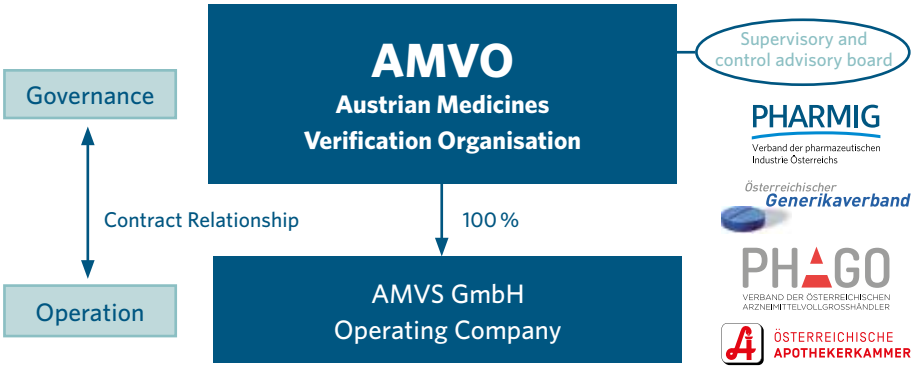
A data repositories system must be set up for this process. The delegated regulation foresees that system will be set up by the pharmaceutical manufacturers and authorisation holders, with the involvement of the other stakeholders (e. g. wholesalers, parallel traders and pharmacists).

The authorities must be given the opportunity to check and monitor the system. This system, the European Stakeholder Model (ESM), developed by the European associations, foresees that all medicinal products shall be entered by the industry into the so-called "European hub". There, they are then allocated to each national system. If a package cannot be found in a national system (e. g. in the case of individual imports), the hub serves as a data router and forwards the request to the relevant national system in which the number was stored. In this country the serial number is finally deactivated, i. e. the package is booked out of the system. In this manner, all packaging that can be issued in a number of countries (so-called "multi-country packs") can be deactivated in all national systems.



Source: EFPIA

When setting up the national repositories the member states have the possibility to develop their own national systems or to revert to a prefabricated system (blueprint system). An example for a national system is the SecurPharm model in Germany. This already began as a pilot in 2013 and will now continue to run until full operation in 2019.



Implementation in Austria

Pharmig, the Austrian Generics Medicines Association, PHAGO (Austrian Association of Full-Line Pharmaceutical Wholesalers) and the Austrian Chamber of Pharmacists formed the AMVO, the Austrian Medicines Verification Organisation, together in Austria. This was officially registered in the Austrian association register in December 2016 and is responsible for the governance of the medicinal product verification system. This should guarantee that all relevant stakeholders participate in the system by 2019. Simultaneously, the members of the AMVO are obligated to work together in the future to clear up and handle any cases of suspected falsifications. The competent authorities are integrated through the supervisory and control advisory board and can therefore fulfill their sovereign supervising tasks.

AMVO formed its own operating company, AMVS GmbH (Austrian Medicines Verification System) for the technical operation of the Austrian repositories system. AMVS GmbH must guarantee the perfect functioning of the national system. All affected stakeholders must connect to the system operated by the AMVS GmbH in order to fulfill their legal obligations.

In 2017, the AMVS GmbH will begin its operations, establish an IT provider for the verification system and start initial test runs.

6 Pharmaceutical industry as an economic factor

6.1 Pharmaceutical production in Europe

Pharmaceutical production in selected European countries

	Euro Million	Euro per inhabitant	estimated population mid 2013
Switzerland*	35,819	4,316	8,299,000
Germany	30,401	377	80,689,000
Italy*	28,696	480	59,798,000
France*	20,981	326	64,395,000
Ireland*	19,305	4,118	4,688,000
Great Britain	17,483	270	64,716,000
Spain*	13,953	303	46,122,000
Denmark*	8,725	1,539	5,669,000
Belgium	9,299	823	11,299,000
Sweden*	6,475	662	9,779,000
Netherlands*	6,180	365	16,925,000
Austria	2,776	322	8,630,000
Finland	1,599	291	5,503,000
Portugal*	1,486	144	10,350,000
Greece	857	78	10,955,000
Norway*	745	143	5,211,000

* Estimates

Source: EFPIA, Statistics Austria, 2015

Switzerland is the leader in pharmaceutical production.

In 2015, Switzerland, Germany, Italy and France produced the majority of pharmaceuticals in Europe.

Ireland and Switzerland reported the highest production value per capita. Austria, with 322,– Euro per capita, is far below the mean value of 910,– Euro per capita of the selected European countries.

6.2 Pharmaceutical production in Austria

Pharmaceutical production in Austria, imports and exports

in Euro million

Source: Statistics Austria

2013
2015

In the pharmaceutical industry Austria is among the exporting countries.
In 2015, the value of medicinal product exports exceeded imports by some 6 %.

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

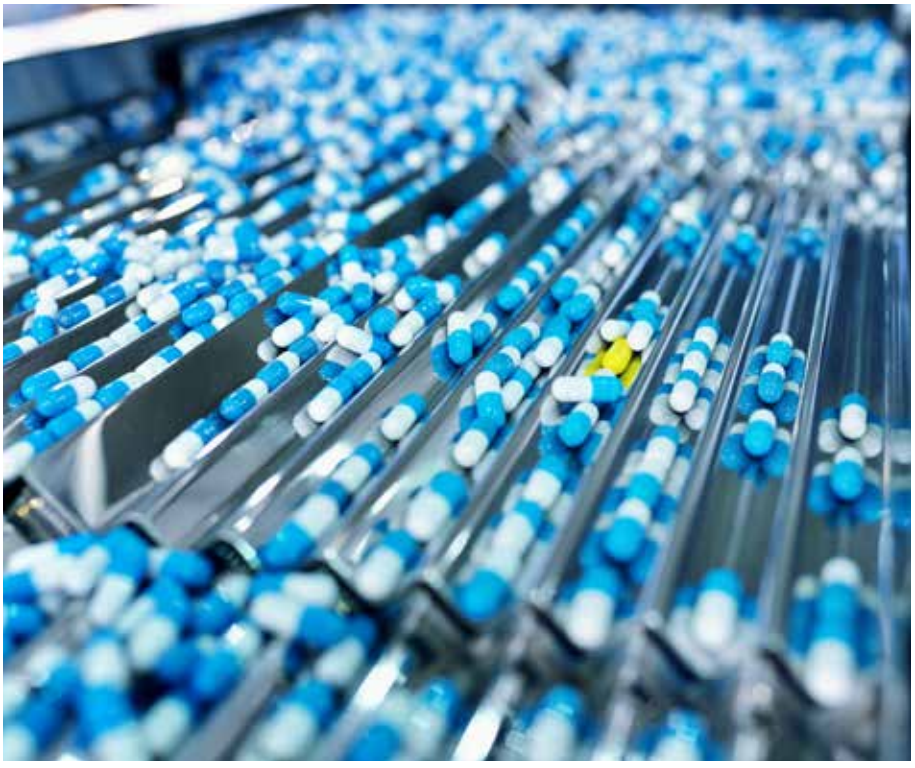
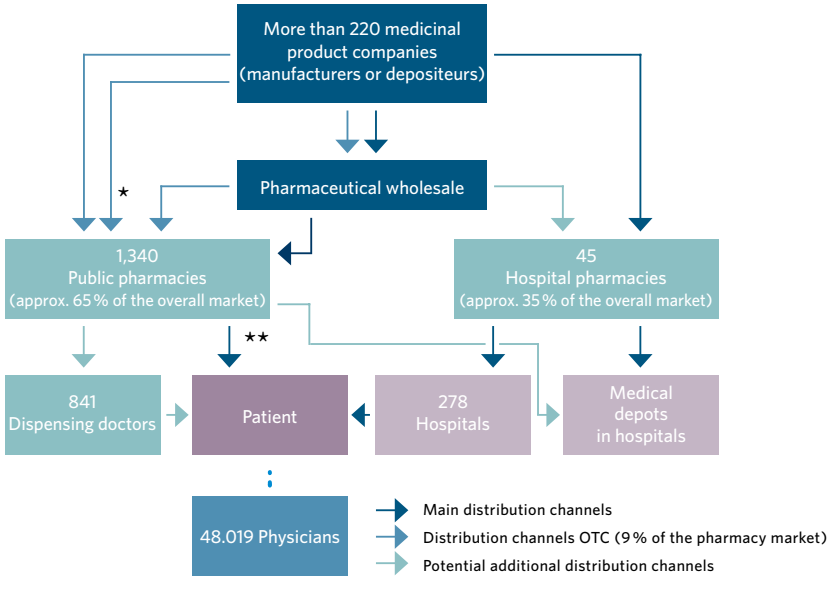


Foto: istock

6.3 Pharmaceutical distribution

The Austrian medicinal product distribution system

In Austria the medicinal product distribution is covered by the following distribution chain: pharmaceutical companies – pharmaceutical wholesalers – pharmacies – patient



Source: Pharmig, Statistics Austria, IMS, HV, BMGF, 2016

* Pharmaceutical logistic companies: in order to guarantee the supply of medication, the Austrian pharmaceutical companies also employ the services of pharmaceutical logistics companies (shipping companies).

** as of 25 June 2015 also distance-selling for OTC products

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).

Parallel trade

If a medicinal product is not imported or exported by the manufacturer or marketing authorisation holder, respecitvely, but by a third party which parallel imports/exports the medicinal product by a distribution channel which is not defined by the manufacturer or marketing authorisation holder, we call this parallel trade.
In many EU member states medicinal product prices are directly or indirectly regulated by the respective national government. Therefore it is possible that the prices for a particular medicinal product are different in various countries which makes it attractive for parallel traders to purchase medicinal products in low-price countries and to import them into high-price countries. Due to the EU principle of free movement of goods this parallel trade is legal, however it involves some risks. Manufacturers are not able to calculate the flows of goods wherefore shortages of supply could occur. The law requires that labelling is adapted to the respective national standards wherefore medicinal products are repackaged and a patient information leaflet in the respective national language is inserted. It is not unusual that medicinal products are resold via several intermediaries until they are accessible for the patient on the domestic market. These measures increase the potential that falsified medicinal products enter the legal distribution chain.
For healthcare organisations which resort to these imports cost savings are usually very slight, because the major part of the price difference benefits the parallel trader.

Distance selling

Distance selling, as defined by the Medicinal Products Act (MPA), is the selling of medicinal products that do not require prescription by a public pharmacy through means of distance communication, e. g. via internet trade.

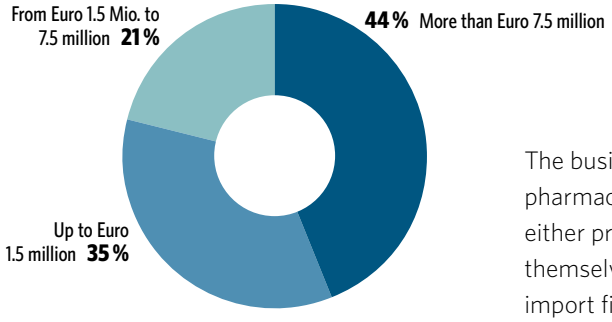
The implementation of the "falsification directive" (2011/62/EU) created a standardised logo for all member states to designate authorised internet pharmacies, leading to the introduction of distance selling, also in Austria.

In the case of orders from an Austrian internet pharmacy, there must be an Austrian flag symbol. Internet pharmacies that operate from other EU countries can also be recognised by their respective flag symbol. Legal internet pharmacies may only sell medicinal products in or to Austria that do not require prescription.

Since 25 June 2015 domestic distance selling is also possible for Austrian pharmacies. The list by the AGES MEA – Austrian Medicines and Medical Devices Agency contains information in all distance selling pharmacies registered in Austria:
https://versandapotheken.basg.gv.at/
Legal provisions are set out in the Ordinance on Distance Selling.

6.4 Company structure

Size of pharmaceutical companies, by turnover



Source: Pharmig, 2016

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.

Pharmaceutical location Austria

The pharmaceutical industry is an important economic factor in Austria. It contributes significantly to the creation of value in the local site and works actively to strengthen it as an economic, production, research and studies site. Every single company provides a significant contribution to the Austrian economy and the best possible health care. The interactive map under www.pharmastandort.at visualises the performance of the industry and shows what companies are constantly working for Austria. The added value created through the pharmaceutical industry in a further sense* amounts to € 9.6 billion, which corresponds to around 2.8% of the GDP. The people employed in the pharmaceutical industry (approximately 18,000 jobs) create more than 63,000 jobs in the economy due to indirect effects.

Source: Life sciences and pharma: Economic Impact Analysis 2016

* included companies that are active in the following areas: research & development, sales, delivery, manufacturing

7 The pharmaceutical market

7.1 Market factor price

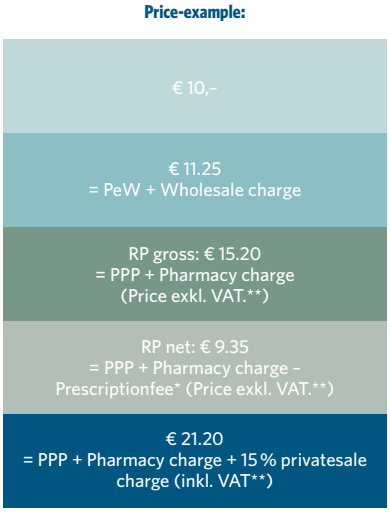
Prices of medicines

- Price ex works (PeW/DAP):
  Manufacturer/Depositeur –› Wholesale

- Pharmacy purchase price (PPP):
  Wholesale –› Pharmacy

if reimbursed:
- Reimbursement price (RP):
  Pharmacy –› health insurance

if a private purchase:
- Pharmacy selling price:
  Pharmacy –› Customer



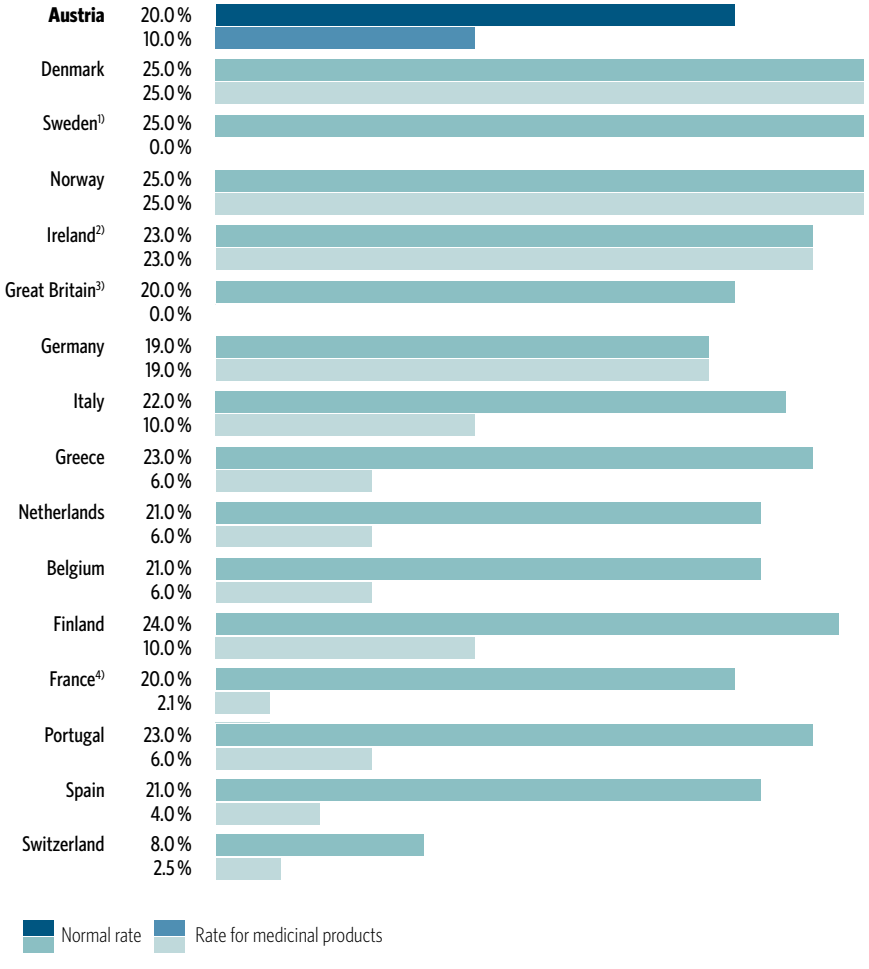
* Prescriptionfee since 1.1.2017: € 5.85; ** VAT. since 1.1.2009: 10 %

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 2017 (since the 1st of January) amounts to € 5.85 per Pack.

Value-added tax (VAT) in Europa per 1.1.2017



Source: European Commission

[1] Sweden: 0 % on prescription. 25 % for OTC

[2] Ireland: 0 % for oral form of administration, 23 % 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

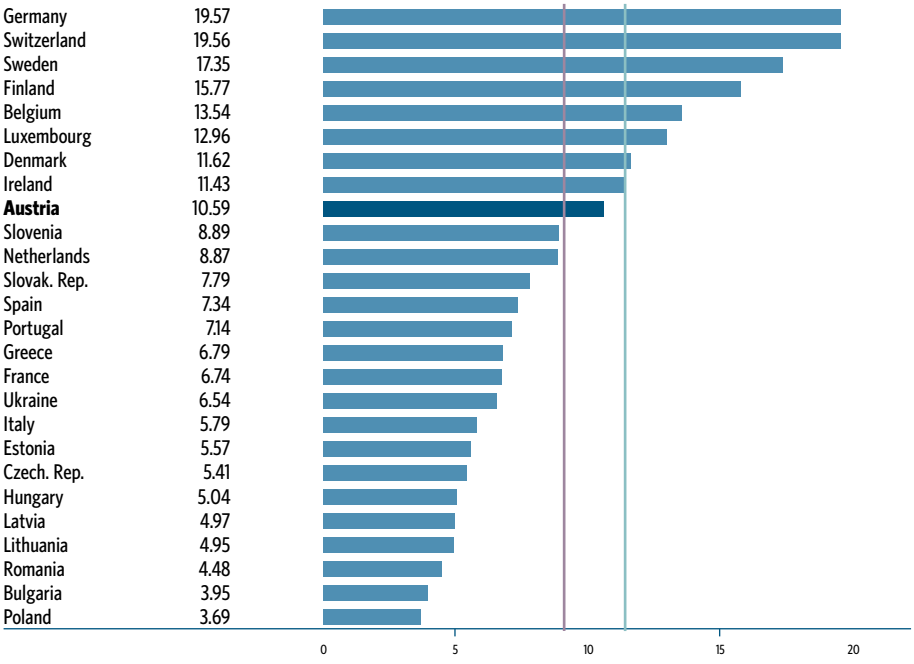
Since January 1, 2009, a reduced VAT rate of 10 % applies to pharmaceuticals in Austria.

Price ex-works (PEW) per pack in the pharmacy market

In 2014 the Austrian price ex-works (PeW) per pack pro was 10.59 Euro and therefore 6.7 % below the EU-15 average of 11.35 Euro.

Germany occupied top position with a PeW per pack of 19.57 Euro, followed by Switzerland at 19.56 Euro per medicinal product pack. Poland and Bulgaria have the lowest PeW per pack, and are at the bottom of the European comparison.

Price comparison per pack (PEW), 2014



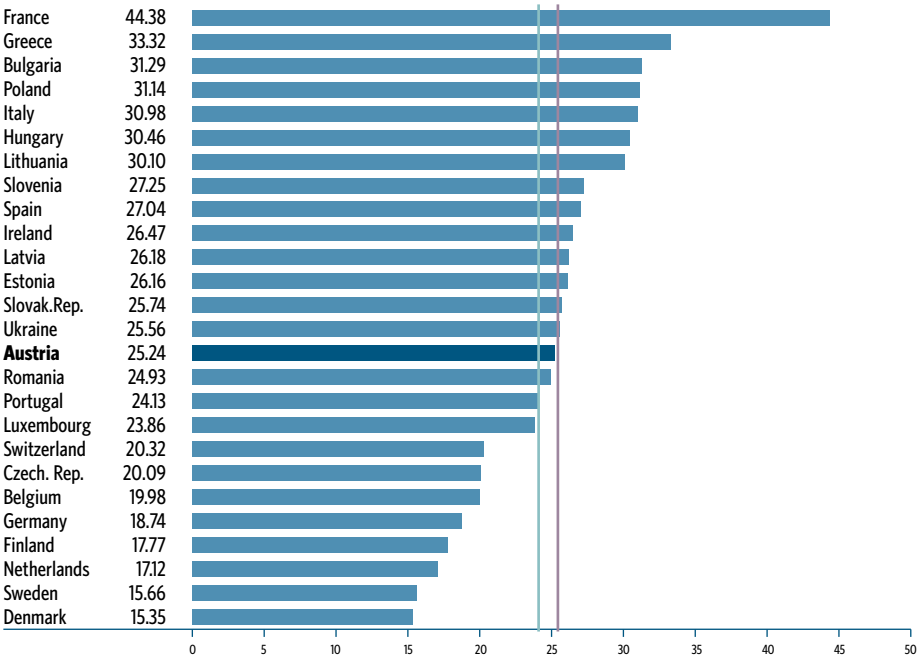
in Euro

Source: calculated by the Institute for Pharmaeconomic Research (IPF) using IMS data

Arithm. Mean EU-25 incl. CH = 9.09 Euro

Arithm. Mean EU-15 incl. CH = 11.35 Euro

Consumption in the pharmacy market, 2014

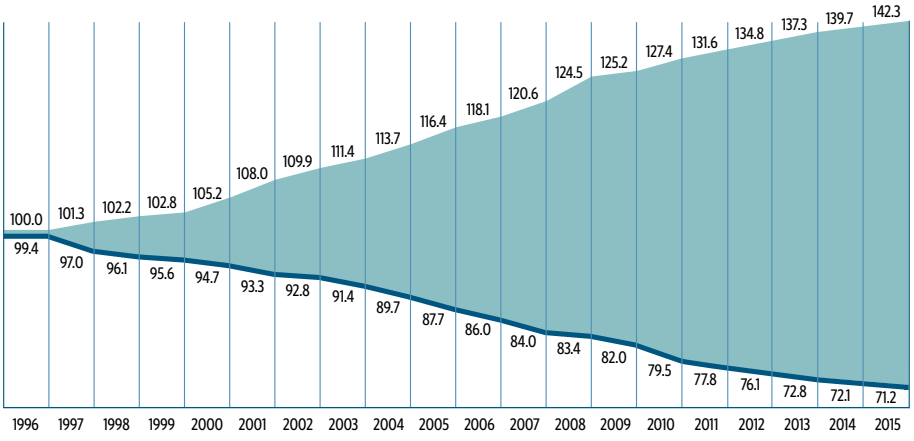


Quelle: IMS Health, IPF eigene Berechnungen

The use of packaging has increased continually in the past years in Austria: In 2008, the number of disposed packages per person was 24.36 vs. 25.24 in 2014.

Despite increases in the per person packaging consumption, the Austrian consumption was 0.47 % below the average of the large country sample. The leader in packaging consumption is France with 44.38 packages per person. Greece takes second place with an average of 33.32 packages per person. The lowest packaging consumption is found in Denmark with 15.35 packages on average.

Price trends (based on wholesale purchasing price)



in percent

Source: Statistics Austria, IMS

Consumer price index* (annual average). CPI 96 (1996=100)

Pharmaceutical price index** (based on wholesale purchasing price)

* The consumer price index (CPI) is the standard index for general pricing trends and inflation in Austria.

** The pharmaceutical price index (based on wholesale purchasing price) is based on IMS calculations and is an element of growth. The pharmaceutical price index incorporates changes in pricing (in per cent) of products which have already been placed on the market in comparison with the previous period, cf. page 57.

Prices for medicinal products already on the Austrian market have decreased annually since 1996: The price for a fictitious package of medicine costing 10 Euro in 1996 is only 7.12 Euro in 2015.

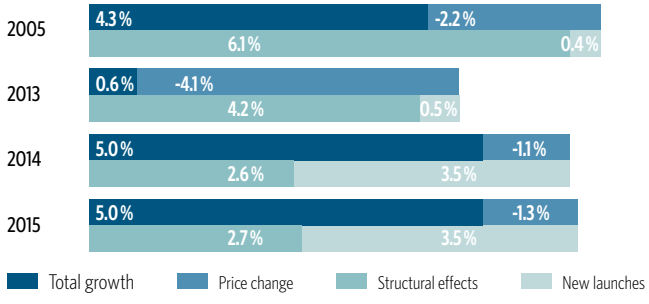
The CPI (consumer price index), however, underwent the exact opposite development.

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

7.2 Elements of growth

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

Elements of growth (based on wholesale purchasing price)



Source: IMS

• 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.

• 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: Following factors are relevant:

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.

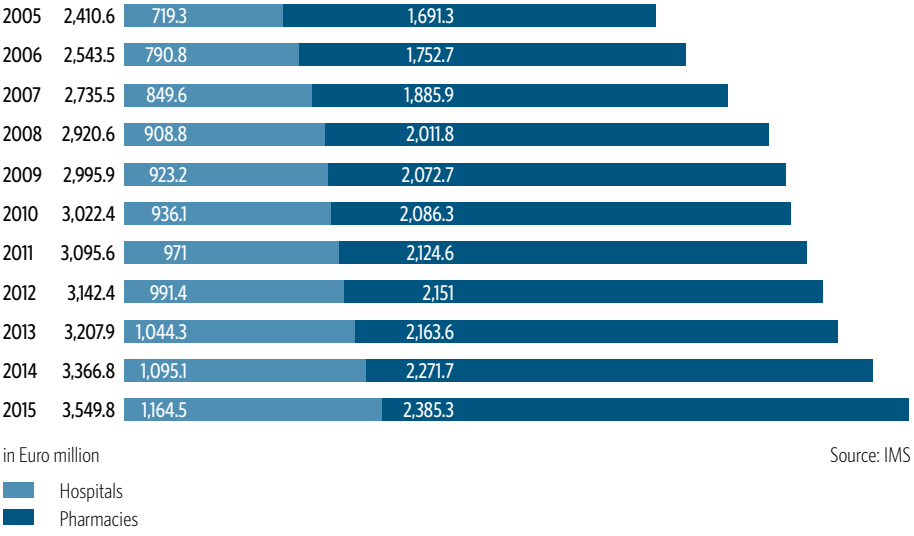
7.3 The hospital and pharmacy market

In 2015, the Austrian medicinal product market reported sales of 3.55 billion euros and a sales volume of 240.7 million packages. This represents a growth rate of 5.4 % in value and a growth rate of 1.6 % in volume.

From the perspective of the manufacturers and distributors the medicinal product market is divided into two segments:

- Hospital market (intramural sector)
- Public pharmacies and dispensing doctors (extramural sector)

Pharmaceutical sales (based on wholesale purchasing price)

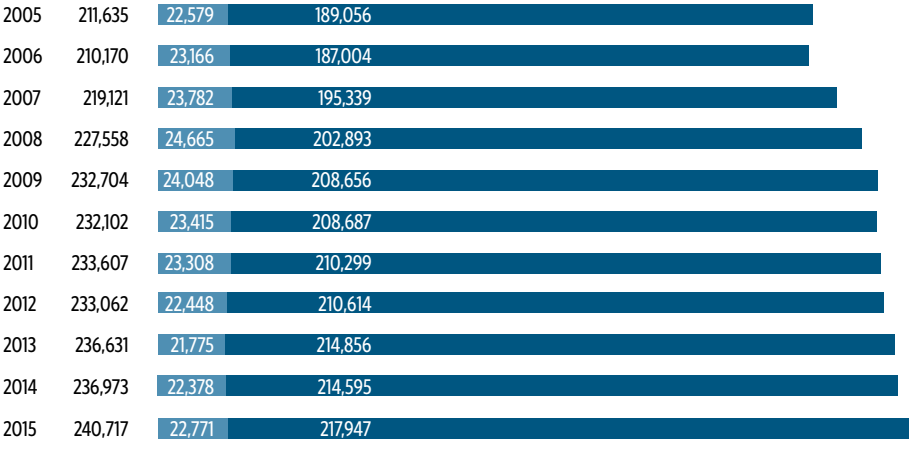


In 2015, both the pharmacy market and the hospital market increased in value and quantity:

- Pharmacy market: + 5 % regarding value according to € in turnover or + 1.6 % regarding quantity according to packages
- Hospital market: + 6.3 % regarding value according to € in turnover or + 1.8 % regarding quantity according to packages

In 2015, 240.7 million packages were sold in Austria. Around 10 % of these went to hospitals (hospital pharmacies) and around 90 % to pharmacies in the extramural sector.

Sold packages



in units of 1,000

Source: IMS

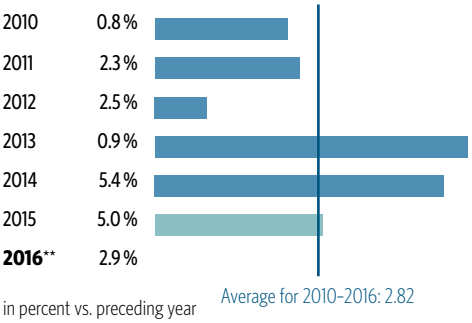
Hospitals
Pharmacies

In 2015, the number of sold packages have increased by 1.6 %.

7.4 The reimbursement market

The market for reimbursable medicinal products is the market segment that includes medicinal products whose costs are assumed by the individual social insurance institutions.

Change rates for expenditures for medicinal products*



in percent vs. preceding year

Source: HV

* Expenditure for medicinal products without VAT and before deduction of prescription charges
** preliminary conduct HV

In 2016, the expenditures of the health insurers for medicinal products increased by 2.9 % compared to the year 2015.

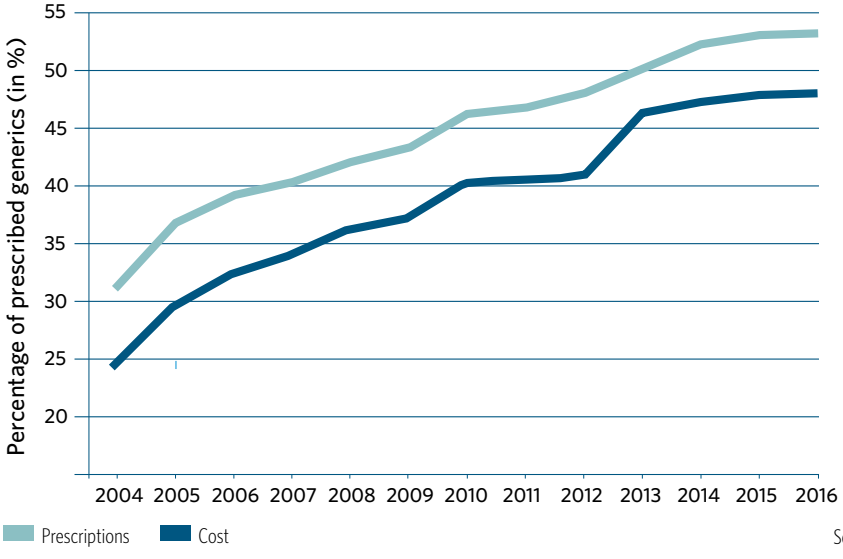
Price ex-works (PeW) per pack in the reimbursement market:

- the domestic price ex-works (PeW) in the reimbursement market is positioned, at 12.34 € per pack in 2014, below the European average (EU-15 average including Switzerland: 12.75 €)
- the health insurance price (incl. 10 % VAT) in Austria's reimbursement market was 17.57 € per pack in 2014, which is also below the European average (EU-15 average incl. Switzerland: 18.75 €)

The management of the health insurance companies and overall spending on therapeutic products can be found in Chapter 9.3.

7.5 Generics in the reimbursement market

Prescribed generic products in the reimbursement market



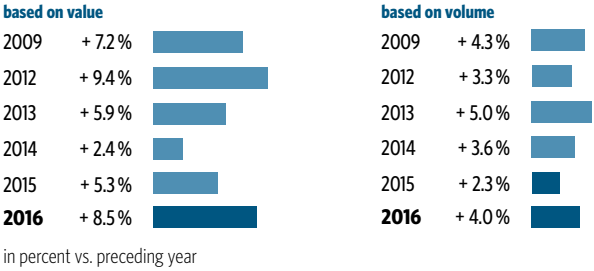
Source: HV

* When calculating the percentage of generics, only the product first added to the reimbursement system (initial supplier) and the products added at a later time (generics) are differentiated.

The percentage of generics in the reimbursement market is about 52 % (according to billing records of the health insurance funds for 2014), this means more than every second prescription is accounted for by a successor product and about 48 % of the costs are accounted for by successor products on the replaceable market.

7.6 Biopharmaceuticals in the reimbursement market

Development of biopharmaceuticals



in percent vs. preceding year

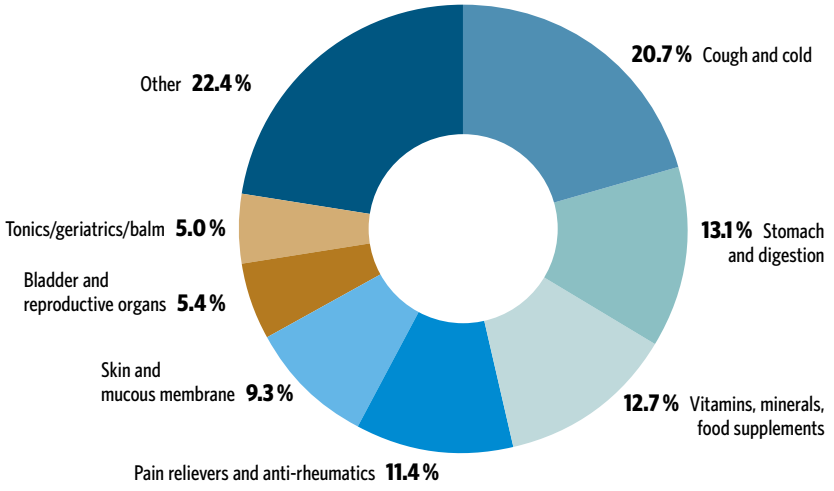
Source: Austrian Chamber of Pharmacists

In 2016 the use of biopharmaceuticals in the health fund market rose 8.5 % in terms of turnover. Volume-wise the market expanded by 4 %.

7.7 The self-medication market

The OTC market grew in value in 2016 compared to 2015 by 2.2 % to € 821.3 million on the basis of the pharmacy sales price and consists of 47% in registered and 53 % in non-registered products.

Indication groups in self-medication (based on pharmacy sales price)

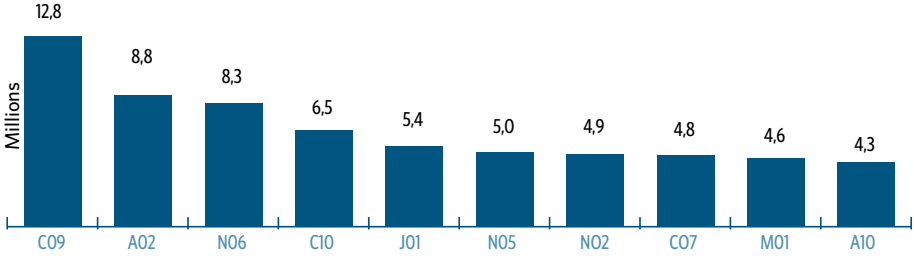


Source: IGEPHA/IMS

The Top 3 cough/cold, stomach/digestion and vitamins, jointly cover 47 % of the self-medication market.

7.8 Pharmaceutical consumption by indication group

The indications group with the highest prescription share was treatment subgroup ATC level 2*, 2014



C09 Medicine for treating the renin-angiotensin system (e. g. with high blood pressure, chronic cardiac insufficancy)
A02 Medicine for the treatment of acid complaints (for neutralising stomach acid, e. g. with heartburn, acid indigestion)
N06 Psychoanaleptics (treatment of psychological illnesses such as depression, dementia, ADHD)
C10 Lipid lowering medicine (to counter metabolic disorders, e. g. with high cholesterol levels)
J01 Antibiotics for systemic use (e. g. penicillin)
N05 Psycholeptics (for treatment of psychotic illnesses such as psychosis, schizophrenia. Medication for the treatment of sleep and anxiety problems)
N02 Analgetics (pain medication)
C07 Beta-adrenoreceptor antagonist medication (e. g. for high blood pressure, cardiac insufficiency, angina pectoris)
M01 Antiphlogistics & anti-rheumatics (inflammation-inhibiting medication for diseases of the muscles and skeletal system)
A10 anti-diabetics (medicine against diabetes)

in packs

Source: HV

* ATC Code: Anatomical Therapeutic Chemical Classifikation System of the WHO

The most frequently prescribed medications according to the ATC system are: Medicines for the treatment of the renin-angiotensin system (e. g. with high blood pressure), medicine for the treatment of acid complaints (e. g. heartburn) and psychoanaleptics (for the treatment of psychological illnesses, e. g. depression)

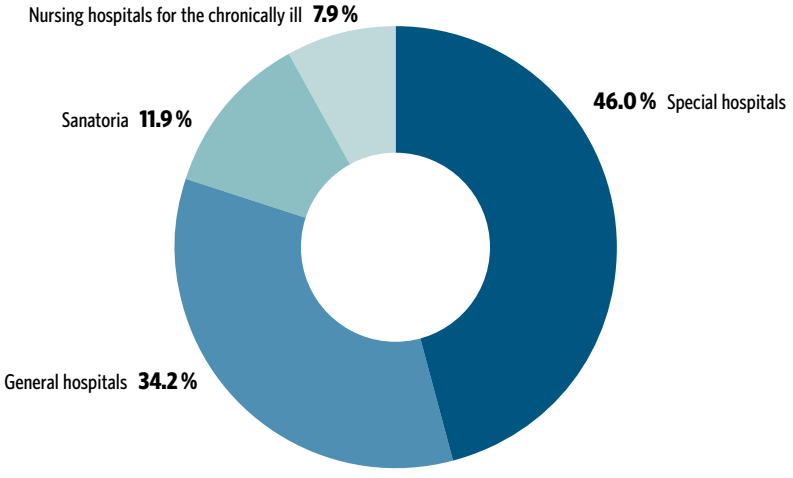
8 Hospitals in Austria

In Austria, hospitals totalled 278 at the end of 2015.
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 statues.

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

- **General hospitals:** for persons irrespective of their gender, age or the type of medical care they receive.
- **Special hospitals:** for the examination and treatment of persons with specific diseases or of persons of a particular age or for certain purposes.
- **Homes for convalescent:** Persons requiring medical treatment and special care.
- **Nursing hospitals for chronically ill:** Persons requiring medical treatment and special care.
- **Sanatoria:** Hospitals with special equipment for special care and accommodation.
- **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.

Types of hospitals (without independent out-patient clinics) 2015



Source: Statistics Austria, BMGF

Hospitals run by social insurance institutions

In 2015 the Austrian social insurance institutions (health, accident and pension insurance institutions) ran a total of 195 own hospitals:

- 120 independent out-patient clinics
- 28 other out-patient clinics/examination centres
- 47 own hospitals for inpatient treatment (= 6,401 beds)

Independent out-patient clinics
38 general hospitals with 115 out-patient or specialist wards
80 dental out-patient wards
2 centres for out-patient rehabilitation

Other out-patient clinics
28 other out-patient clinics (to carry out adolescent, convalescent and other medical examinations)

Own hospitals for inpatient treatment	Beds
1 general hospital and 38 out-patient wards	455
7 accident and emergency hospitals	985
27 special hospitals/rehabilitation centres	3,875
7 sanatoria	638
5 convalescence and recovery homes	514

Source: HV, Statistical Handbook Austrian Social Insurance 2016

8.1 Structural details of hospitals

Of these 278 hospitals, 117 (42 %) are hospitals with public status and 161 (58 %) without public status. Hospitals with public status are not to be confused with hospitals of public agencies and institutions.

Approximately 55 % of hospitals are run by public agencies and institutions.

Ownership/responsible bodies – public law status in 2015

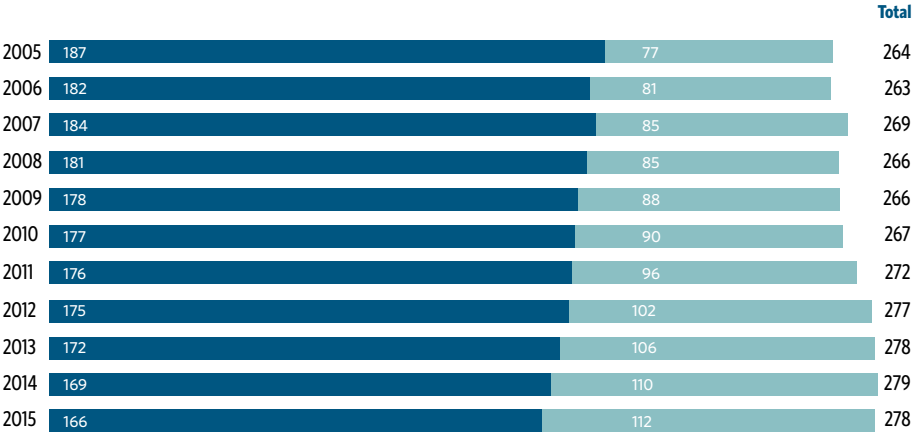
Number of hospitals and beds actually set up	With public law status* 153 hospitals (45,097 beds)	Without public law status** 125 hospitals (20,041 beds)
Public ownership 117 hospitals (43,960 beds)	93 hospitals (36,835 beds)	24 hospitals (7,125 beds)
Private ownership 161 hospitals (21,178 beds)	60 hospitals (8,262 beds)	101 hospitals (12,916 beds)

Source: BMGF

* federal government, provincial and municipal hospital companies, social insurance institutions

** religious orders and congregations, private persons, private companies and associations

Development of hospitals according to care function

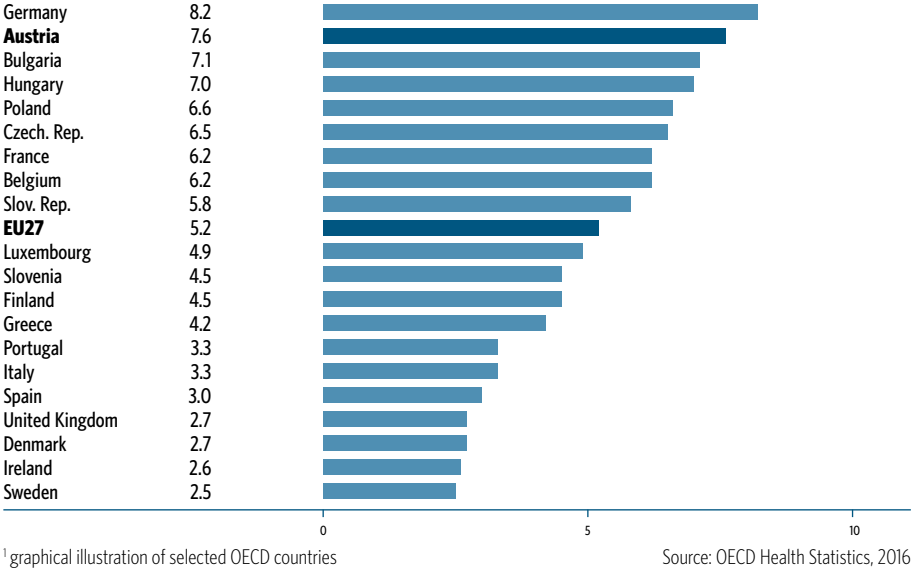


Source: BMGF, Annual Hospital Statistics*

Throughout the years, the number of institutions in the area of acute short-term care has decreased from 187 (2005) to 166 institutions (2015). In comparison to this, the area of non-acute care has increased from 77 institutions (2005) to 112 (2015).

Hospital care in international comparison

Hospital bed capacity per 1,000 inhabitants, 2014[1]



[1] graphical illustration of selected OECD countries

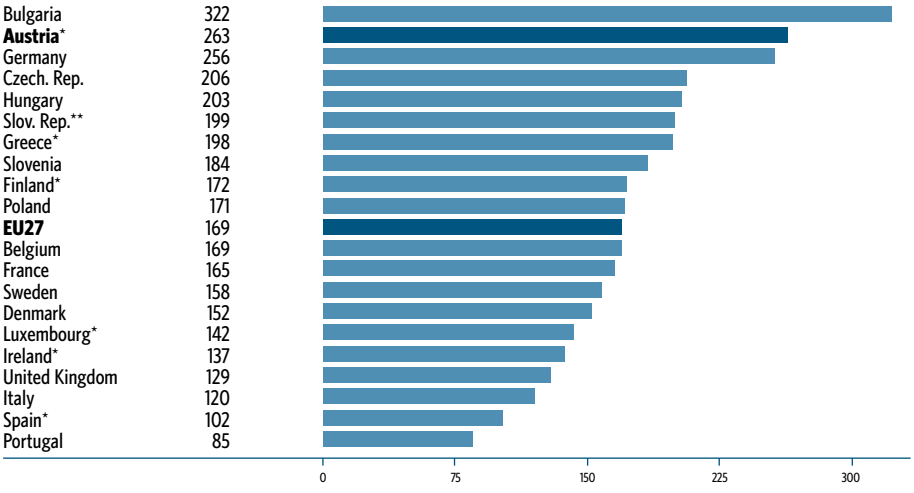
Source: OECD Health Statistics, 2016

Austria has 46 % more hospital beds per 1,000 inhabitants than the average of the EU 27-states.

With 7.6 beds per 1,000 inhabitants, Austria is in second place behind Germany in the European OECD country comparison.

Along with the large availability of hospital beds, Austria also has the highest number of hospital treatments per number of inhabitants, compared to other European countries (263 vs. EU 27 average 169).

Hospital discharges per 1,000 inhabitants, 2014[1]



[1] graphical illustration of selected OECD countries

Source: OECD Health at Glance, 2016

* not including discharges of healthy new-born babies from hospitals (between 3 % and 10 % of all discharges).

** including discharges of day-care cases

Development of bed capacity in Austria

The overview also indicates the actually set up beds in Austria's hospitals (65,138). In relation to Austria's population, the bed coverage was 7.55 beds per 1.000 inhabitants.

Development of bed capacity in Austria per 1,000 in habitants

Quelle: BMGF

In 2015, 2.8 million hospitalisations for in-patient treatment were reported in Austrian hospitals. The hospitalisation frequency (=hospital stays per 100 inhabitants) amounted to 33.2 % (1991: 23.9 %, 2005: 31.8 %).
The average duration in acute hospitals has been constant since 2011 at 6.5 days.

8.2 Hospital funding

The expenditure of Austrian hospitals operating on the LKF basis (system of performance-oriented hospital financing) amounted to 12.8 billion Euro in 2015. Of these, about 60 % were funded by the Regional 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 numbers for hospitals financed through the regional health fund in 2015

	Euro millions
Share from regional funds	7,688
Social insurance*	4,903*
The federation	1,410
Federal states (VAT-funded)	220
Municipalities (VAT-funded)	155
Funder means	1,000
Share from hospital funders	3,912
Federal states, municipalities	2,272
Religious orders and others	1,550
Social insurance	90
Share from private parties	1,200
Patients, private insurances	1,200
Total	**12,800**

in Euro million

Source: calculated by the Institute of Pharmaeconomic Research (IPF) with reference to the following data: HV, BMGF, Austrian Statistics

* In the Austrian social insurance system the area of hospital care incorporates the following expenses: proportionate money transfers to regional health care funds and the Federal Health Agency for Inpatient Care, payments to the remaining hospitals (funds for private hospitals, emergency hospitals, etc.) and payments for hospitals abroad. It does not include expenses for outpatient care. These expenses are recognised as medical attention and equivalent services (outpatient services in hospitals).

Social insurance contributes a large share of hospital funding.
Of Euro 7.7 billion which are financed by regional health insurance funds, 64 % are accounted for by the social insurance system.

9 Health insurance institutions and pharmaceuticals reimbursement

A total of 21 social insurance institutions including 15 health insurance institutions protect insured persons paying contributions (6.4 million; status: 2010) 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 7 institutions, depending on their occupation and the location of the employer. There is no choice (except for those who pursue more than one occupation). The individual health insurance funds are managed autonomously to a large extent, but coordinated by the umbrella organisation Main Association of Austrian Social Insurance Institutions. Besides the health insurances there are 15 medicals care institutions ("KFA") for employees 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. 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 shall not go beyond what is necessary". (§ 133 ASVG)

9.1 The code of reimbursement

Effective January 1, 2005, the previous reimbursement list was replaced by a Code of Reimbursement (Erstattungskodex or EKO). Based on the ASVG (General Act on Social Insurance) a procedural regulation (VO-EKO) governs in detail the process and requirements for the inclusion of a medicinal product in the EKO.

A print version of the whole EKO is published at the beginning of every year, any monthly amendments are published online at www.avsv.at.

The EKO consists of three groups (also called boxes):

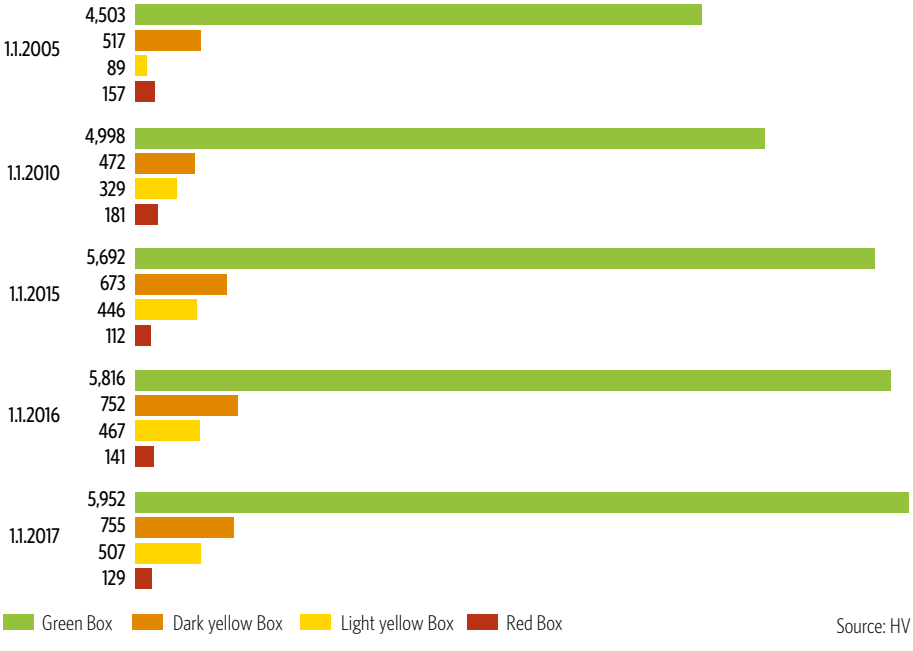
- The **Green Box** comprises medicinal products which are either general dispensable or under specific circumstances in specified amounts. The authorisation of a chief consultant (control physician) belonging to the health insurance is not required if the rules of the Code of Reimbursement are complied with.
- The **Yellow Box** 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

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.

Number of medicinal products in the EKO (acc. to national drug code)



Source: HV

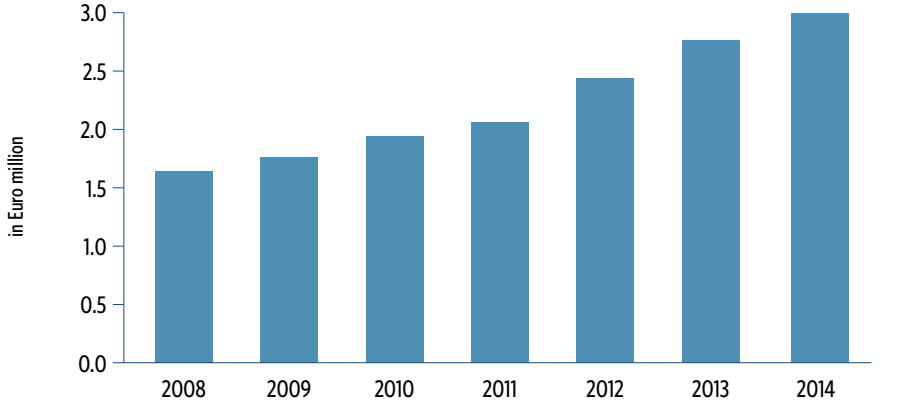
On January 1, 2017, 7,343 packages were listed in EKO, compared to 5,266 when EKO was introduced.

ABS (pharmaceutical approval service) and "obligation for approval by chief physician"

Approval for the prescription of medicines (those listed in the dark yellow and red box or not listed in the EKO at all) is carried out through the e-card infrastructure system (ABS medicines approval service).
Before the contracted 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). This process should take no longer than 30 minutes. Only when the contracted physician has received the "okay" from the health insurance, is he permitted to write a prescription.

In 2014, 121 million prescriptions were reimbursed. Of these, 3.1 million applications for approval were accounted for by prescriptions required prior approval, whereby the number of approval applications has risen continuously in recent years.

Development of approval applications



Source: HV

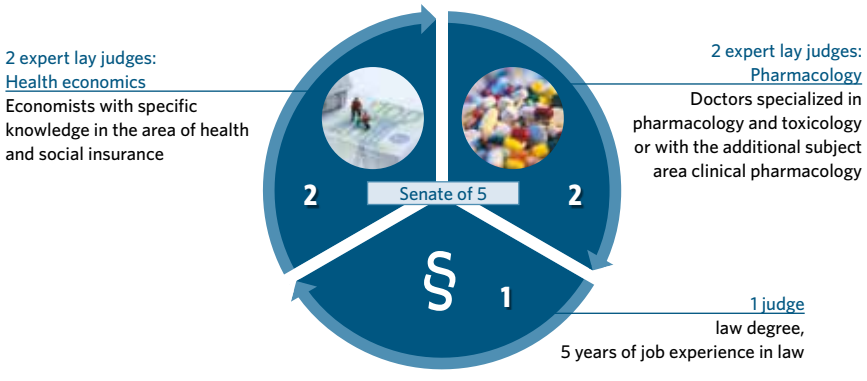
In 2014 there were 3.1 million applications for approval by a "chief physician".

9.2 Federal administrative court

Due to the administrative jurisdiction amendment of 2012, since January 01, 2014, the Federal Administrative Court has been responsible for reviewing decisions of the Main Association of Social Insurance Institutions in accordance with § 351 h ff ASVG (before: the Independent Drug Commission "UHK"). Appeals against decisions of the Main Association of Austrian Social Insurance Institutions must be filed within four weeks of the decision on the website www.sozialversicherung.at. The appeal postpones the implementation of the decision.

Federal Administrative Court:

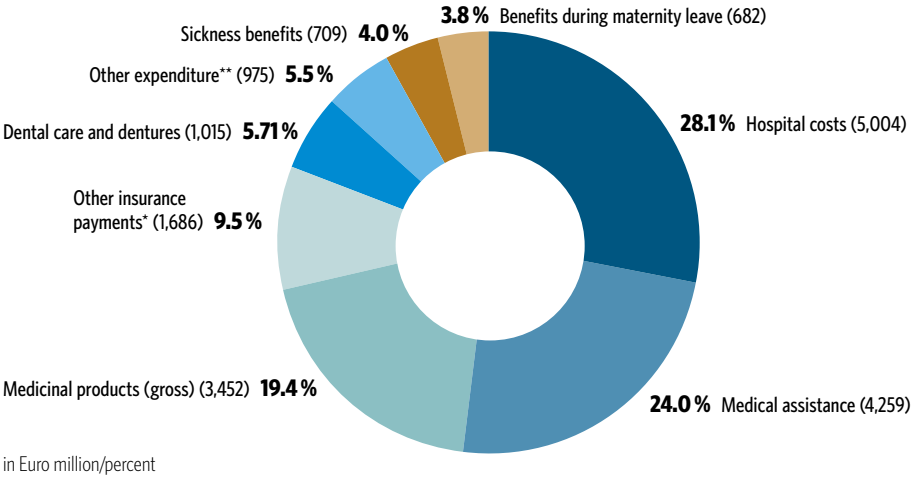
- Jurisdiction according to allocation of responsibilities. Chamber economic matters, legal area: environment matters, referral group: agricultural and health law
- Decision made by senate of 5 (discussion and voting of the senate is not publicly accessible)



- Oral proceeding: upon request or if deemed necessary by the Federal Administrative Court
- The Federal Administrative Court is authorised to
  - decide at the course themselves (as opposed to the UHK, which merely declared decisions invalid) if the requirements are met (§ 28 para 2 of the Law of Administrative Court Proceedings)
  - to nullify the decision by their own resolution – new decision by the Main Association (the Main Association is obliged to the legal opinion of the Federal Administrative Court)
- Representation by a lawyer not obligatory
- The decisions of the Federal Administrative Court are published in the federal legal information system (RIS) at www.ris.bka.gv.at
- Since 1.1.2014 there was a procedure under § 351h ff ASVG in the case of 22 medicinal products (status: February 2016)
- Appeals: Higher administrative court and/or constitutional court

9.3 Budgets of health insurance institutions

Preliminary conduct of the health insurance institutions 2016



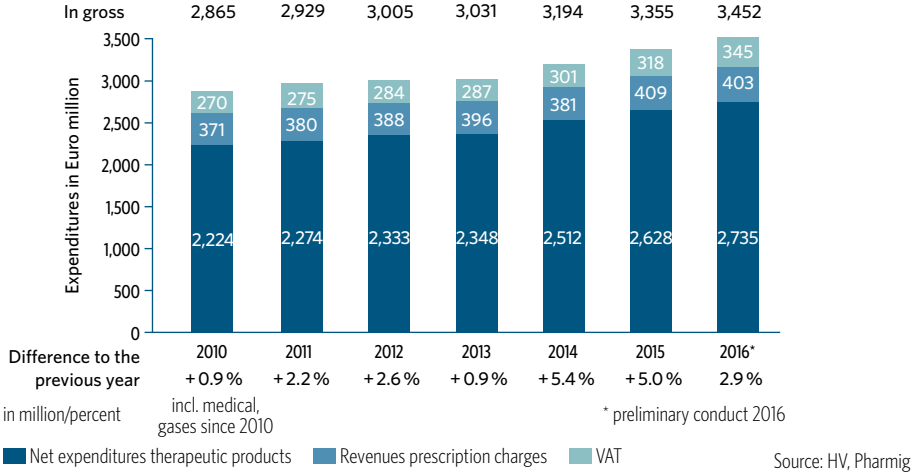
in Euro million/percent

* Rehabilitation, Medical Aids, Transport Costs, Desease Prevention, Early Diagnosis, Home Nursing, etc.

** Administration, Remittance of equalisation funds, Capital Consumption, others

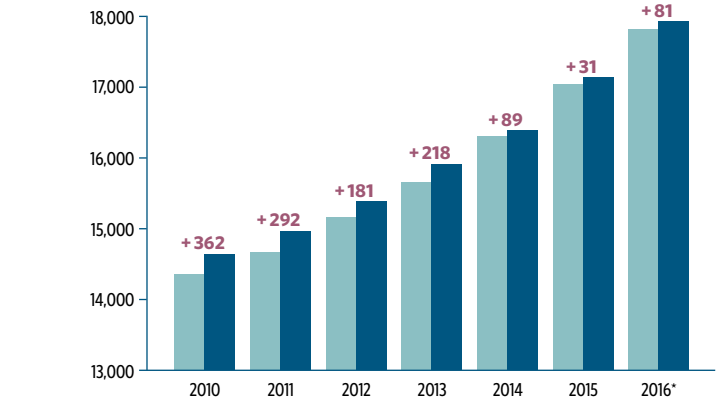
The positions for therapeutic products (gross) include 10 % VAT. Prescription fees received and individual discounts are not considered, solidarity fees as well as individual discounts for pharmaceutical companies.

Expenditures for therapeutic products



Source: HV, Pharmig

Development of the total expenditures/total revenues of the health insurance funds



	2010	2011	2012	2013	2014	2015	2016*
Gesamtausgaben	14,278	14,657	15,189	15,676	16,275	17,088	17,782
Gesamteinnahmen	14,640	14,949	15,370	15,894	16,364	17,119	17,863

in Euro million

* preliminary conduct 2016

Expenditures in total Revenues in total

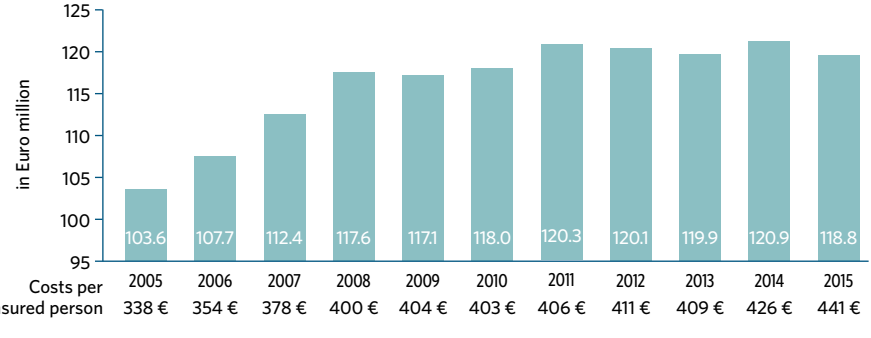
Source: HV

The income from social health insurance carriers amounted to € 17.9 billion according to the preliminary conduct in 2016 (+ 4.3 % vs. 2015), and their expenditure amounted to Euro 17.8 billion (+ 4.1 %). The earnings therefore amounted to EUR 81 million.

9.4 Prescription trends

In 2015 the number of prescriptions (118,802,404 reimbursed prescriptions) decreased by 1.8 %.

Number of reimbursed prescriptions incl. costs per insured person



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Costs per insured person	338 €	354 €	378 €	400 €	404 €	403 €	406 €	411 €	409 €	426 €	441 €

Number of prescriptions

Source: HV

in Euro million

9.5 Co-payment: Prescription fee

There exist numerous co-payments and additional fees which have, as of yet, not been harmonised. All together, in 2016*, the health insurance institutions collected approx. 403 million Euro in prescription fees only. The prescription fee per package of a medicine amounts to 5,85 Euros in 2017. Besides a general exemption of the prescription fee granted to persons based on social reasons there is an annual ceiling on prescription fees since January 2008. This ceiling is 2 % of the annual net income (excluding special payments such as holiday or Christmas allowance) of the person insured. As soon as this amount is exceeded, the person insured and his co-insured dependants do not have to pay the prescription fees for the rest of the respective calendar year.

Development of prescription charge

in Euro

Source: Austrian Pharmacist Chamber

Since 1995 the prescription fee has more than doubled.

When setting the net expenditures of health insurance funds for medicinal products (2016* 2.735 million Euros) off against the prescription charge revenue (403 million Euros), a deductible of 14.7 % remains which is to be paid for the medicinal product by the patient.

Deductible for medicinal products

Source: HV

Medicinal products with prices under the prescription fee are not considered. The patients pay for these medicinal products themselves. The number of these medicinal products increased in 2017 by +7.5 when compared to 2016: In 2017, 1,658 packages were listed in the green box from the EKO (this amounts to 28 % of the packages listed in the green area of the EKO) vs. 1,543 in 2016.

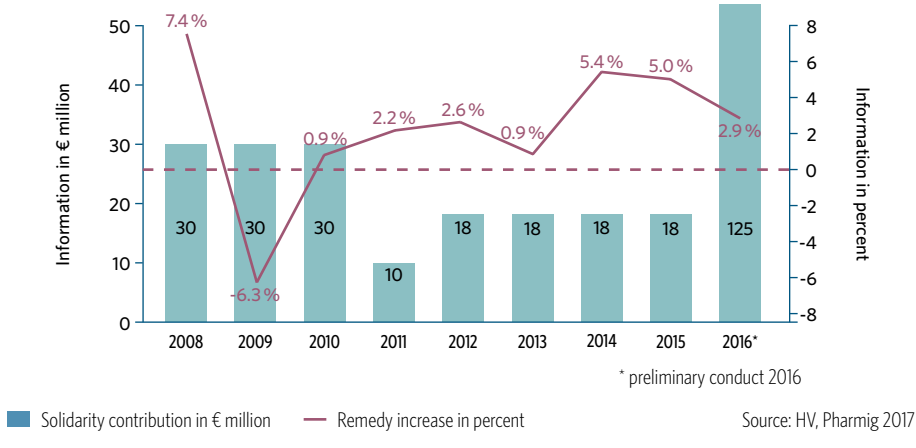
* preliminary conduct

Source: IMS DPMÖ 2017

9.6 Pharma master agreement

Pharma master agreement 2018

The framework pharmaceutical contract is a unique prime example of successful work in Europe. Since 2008, the pharmaceutical industry and social health insurance have been working together on a contractual basis in order to support the efficiency of the legal health insurance companies, in particular with patients. The pharmaceutical industry is committed to further strengthening the health care industry.
104 pharmaceutical companies and 7 medicinal product wholesalers contribute with the Pharma Master Agreement 2018 (term 1.1.2016-31.12.2018), shall further make social contributions totalling several millions to the domestic health insurance institutions: 125 million Euro in 2016, and a total of up to 160 million Euro in 2017 and 2018 (depending on the actual increase in spending on medicinal products).
During the three-year term, the common healthcare objective will also be continued. An earmarked amount of 6.4 million Euro in total is thus available for projects relating to child health and prevention.



During the three-year term, the common healthcare objective will also be continued. An earmarked amount of 6.4 million Euro in total is thus available for projects relating to child health and prevention.

Health objectives committee – funding focus & projects

The joint health objectives agreed upon in the extension of the Pharma Master Agreement entered into by the pharmaceutical industry and the health insurance funds are implemented by a committee with equal representation. After its inauguration in fall 2011, the first selected projects were presented at the end of 2012.

Funded projects from the joint health objectives set out in the pharma master agreement – Funding priorities per year:

2012: Paediatric and adolescent health
2013: Addiction and psychosocial health as related to prevention
2014: Measures for strenthening health competence related to health promotion and prevention
2015: Measures for promoting equal opportunities in healthcare within the framework of intersectional cooperations

The submitted projects are processed professionally and subjected to an evaluation process according to previously defined assessment criteria. The selected projects are intended to act as models for an improved healthcare provision to politicians and other partners in the healthcare system. Previous projects were presented to a wide specialist audience in November 2015 under the title "Celebration for Paediatric Healthcare". This initiative conducted in partnership between the pharmaceutical industry and social insurance institutions, which is probably unique in Europe, supplements the efforts of state healthcare policies to advance the healthcare system.
More information at www.pharmig.at

2016: Measures to promote healthier nutrition, healthy movement and mental health

No.	Project title	Applicant	Scope
1	Health of Austrian apprentices	Insurance Institution of the Austrian Railways and for the Austrian Mining Industry / IfGP	Nationwide
2	MANTR–a – anorexia therapy for adolescents	Medical University Vienna	Vienna, NÖ, Bgld.
3	A closer look at food	AGES	Nationwide
4	feel free and healthy – cheers to us!	PGA – Association for Preventive Health Work	Upper Austria
5	Small lighthouse	Association Dialogue	Vienna
6	MIG 2020	Working Group for Health Promotion	Vienna, NÖ, OÖ, Styria
7	Educational health coordination in Bregenz	State Capitol Bregenz	Bregenz
8	App dich fit	Styria vitalis	Nationwide
9	Work title: "Power for Life"	Social Security Institution for Farmers	Nationwide
10	Learning without noise	Umweltdachverband GmbH	Nationwide
11	NF1 – I am there, I know my way around	Medical University Vienna	Nationwide
12	moving spaces – participative spaces for movement	OPK – offenes PlanerInnenkollektiv	Vienna
13	Youth & Amber	Diakonie Flüchtlingsdienst gem. GmbH	Vienna, NÖ
14	You rock!	Kärntner Insurance Scheme	Klagenfurt

PP = Practice-based project RP = Research project

10 Pharmig code of conduct

The Pharmig Code of Conduct regulates the communication and relationship with laypeople, physicians and other healthcare professionals. Apart from the General Principles, the Code of Conduct sets out rules concerning information on medicinal products, advertisement for medicinal products, information and advertising via the Internet, events, cooperation with healthcare professionals and intitutions, as well as patients' organisations, disclosure of Transfers of Value, company employees, clinical trials and violation of the Austrian Medicinal Products Act (MPA).

Transparency creates trust

Transparency provisions have already been introduced in 2009 in order to support patients' organisations and in 2013 for donations and subsidies for institutions which primarily consist of healthcare professionals. The CoC amendment of 2014 contributes to more transparency in the cooperation with healthcare professionals and institutions. In future, all Transfers of Value by pharmaceutical companies in connection with medicinal products which require proscription must be documented and disclosed. Healthcare professionals and institutions must be designated as benefit recipients.

The duty to disclose applies only to Transfers of Value in connection with:

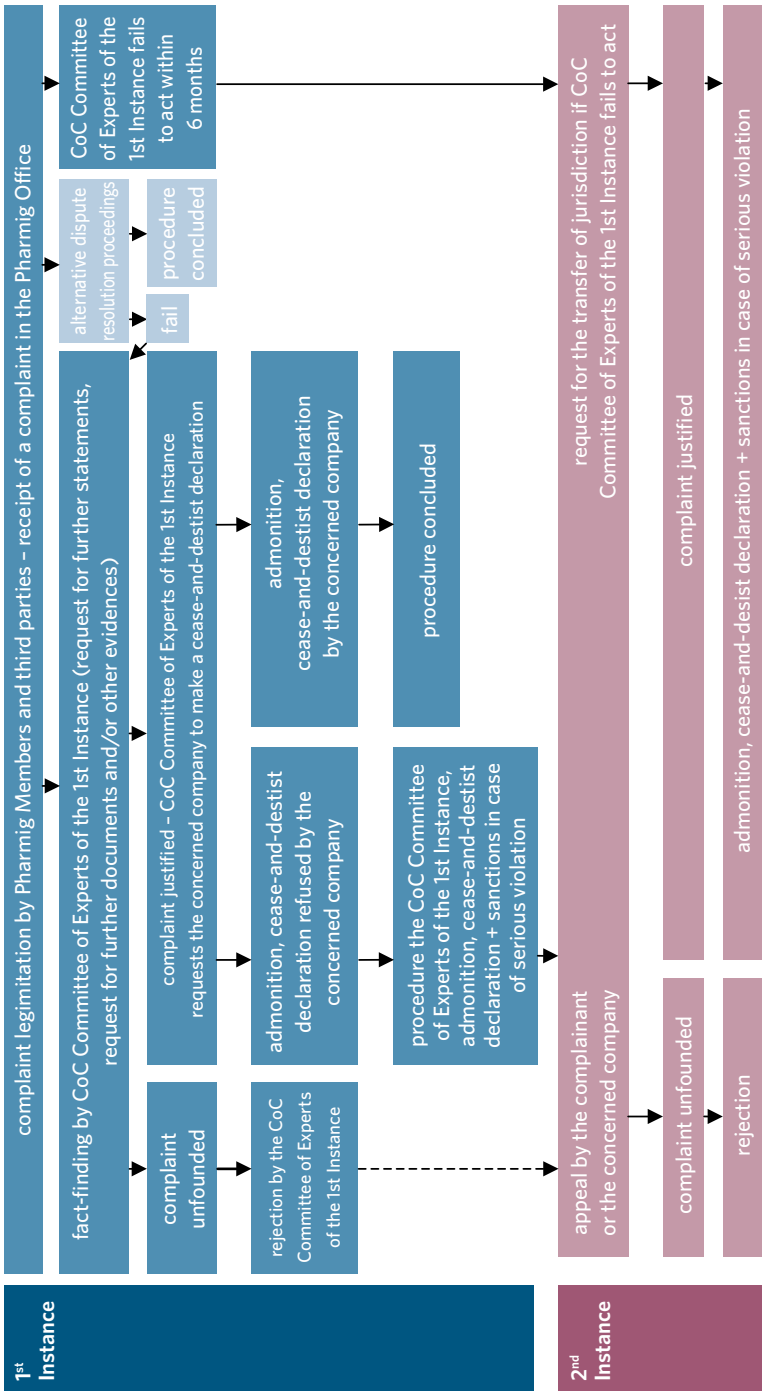
- Research and development
- Donations and subsidies
- Events
- Services rendered and consulting provided including expenses incurred

In principle individual disclosure of Transfers of Value which result from these cooperations should be aimed at. For individual disclosure it is necessary to seek consent. All applying data protection provisions must be complied with. In the case that there is no consent, disclosure must be conducted in aggregated form. The data shall be disclosed annually (as per 30.6.) on a publicly accessible homepage, for the first time in 2016 for the year of 2015. You can find more information on the transparency-initiative under: www.transparenz-schafft-vertrauen.at.

Ethical standards of the pharmaceutical branch

This voluntary self-regulation through the Pharmig Code of Conduct bears witness to a keen sense of responsibility and the express will of our members toembrace the high ethical standards of our branch. Non-members or third parties are given the opportunity to file complaints against alleged infringements of the Code of Conduct. For this purpose, a written Code of Conduct agreement needs to be signed for the relevant proceedings. Since 2007, complaints can be filed anonymously if they involve infringements of article 7 (events) and article 11 (benefits). In 2015, the additional possibility of a dispute resolution procedure was adopted into the VHC code of procedure.
In 2015 there were 4 new VHC complaints, three of which were anonymous. Furthermore, a complaint from 2014 was resolved. To ensure legal security and to better understand the practical application and design of each individual VHC provision, the results of the procedures carried out and completed since the taking effect of the VHC code of procedures will be published in anonymised form on our website www.pharmig.at.

Flowchart – procedure of the COC committees of experts of the 1st and 2nd instance



11 Laws and regulations

The table below lists the major laws relating to the development, production, evaluation, marketing authorisation and the distribution of medicinal products. Further information can be downloaded under www.pharmig.at

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)
Health and Food Safety Act	Spin-off of responsibilities and procedures reg. the medicinal product system from the BMGF to the Austrian Medicines and Medical devices Agency
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 "Human 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
Federal Administrative Court Act (BVwGG)	Governs the organisation of the Federal Administrative Court
Administrative Court Procedural Act (VwGVG)	Governs the procedures at the Federal Administrative Court
EU-delegated regulation on safety features (Reg 2016/161)	Governs the technical specifications, modalities of the verification, characteristics of the repository system and derogations for the safety features appearing on the packaging of medicinal products for human use

National regulation	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) contains planning, inspection, authorization of non interventional studies; relevant for pharmaceutical companies who plan, implement, inspect/or finance a NIS
Ordinance on Distance Selling	Sales of medicinal products via distance selling

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, cooperation with members among experts, institutions and patientorganisations
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 economic prescription of medicinal products and curing aids	RöV	Cost guidelines of the health insurance
Principles of the HEK (Medicinal Product Evaluation Commission)	HEK	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

12 Abbreviations

AGES	Agency for Health and Food Safety
ASVG	General Social Insurance Act
AMVO	Austrian Medicines Verification Organisation
AMVS	Austrian Medicines Verfication System
BASG	Federal Office for Safety in Health Care
BMGF	Federal Ministry for Health and Women
BVG	Austrian Constitutional Law
CPI	Consumer Price Index
DCP	Decentralised Procedure
EFPIA	European Federation of Pharmaceutical Industries and Associations
EKO	Code of Reimbursement
EMA	European Medicines agency
FAC	Federal Administrative Court
GDP	Gross Domestic Product
GESG	Health and Food Safety Act
GMP	Good Manufacturing Practice
HEK	Medicinal Products Evaluation Commission
HV	Main Association of Austrian Social Insurance Institutions
ICD10	International Classification of Deseases and Related Health Problems
IGEPHA	The Austrian Self-Medication Industry
IMS	IMS Health
IPF	Institute of Pharmaco-economic Research
IKF	Performance-oriented Hospital Financing
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition
MPA	Medicinal Product Act
NIS	Non-Interventional Study
OECD	Organisation for Economic Cooperation and Development
OeGV	Austrian Generics Medicines Association
OTC	Over The Counter
PEW	Price Ex Works
PHAGO	Austrian Association of Full-Line Pharmaceutical Wholesalers
PV	Pharmacovigilance
R&D	Research & Development
SHA	System of Health Accounts
SPC	Supplementary Protection Certificate
UHK	Independent Medicinal Products Commission
VAT	Value-Added Tax
VHC	Pharmig Code of Conduct
WKÖ	Austrian Federal Economic Chamber

PHARMIG

Verband der pharmazeutischen
Industrie Österreichs