Facts & Figures 2023

Medicinal Products and Health Care in Austria

PHARMIG

Association of the Austrian Pharmaceutical Industry

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Imprint

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PHARMIG – Association of the Austrian Pharmaceutical Industry
Mag. Alexander Herzog, General Secretary
Operngasse 6, 1010 Vienna

Phone: +43 1 4060 290-0
E-Mail: office@pharmig.at
Web: www.pharmig.at
ZVR-number: 319425359

Editorial staff
Mag. Julia Girardi, MBA, MSc
Mag. (FH) Martina Dick
Maximilian Weissengruber, BA

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Content

PHARMIG at a glance

PHARMIG – the Association of the Austrian Pharmaceutical Industry – is a voluntary and 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 % of the Austrian medicinal product market.

PHARMIG and its member companies are committed to secure the 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 relies on intensive cooperation between 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 health care system and relevant policy areas. In so doing, PHARMIG demands fair, reliable and calculable framework conditions for the pharmaceutical industry which serve all stakeholders 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.

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Dear readers!

Reliable information provides orientation, security, and the foundation for valid decisions. This is all the more true in times of crisis.

I am pleased to present the latest and completely redesigned edition of Facts & Figures 2023. As usual, we provide you with comprehensive information about the Austrian health care system.

With our Facts & Figures 2023, we once again want to make a fact-based contribution to the dialogue and joint discussion on current and future challenges that Austria as a healthcare and pharmaceutical location is facing.

In this edition we have again incorporated some novelties for you: The approximately 80 graphs and tables have been redesigned and a short introduction and overview has been added to each chapter.

Facts & Figures 2023, together with selected graphs and the German version „Daten & Fakten 2023“, are available for download on our website www.pharmig.at.

I hope you have an interesting read and gain a lot of knowledge with our Facts & Figures 2023!

Kind regards,

Mag. Alexander Herzog
Secretary General, PHARMIG

approx. € 52.1 billion

were spent on healthcare in 2021
(equivalent to approx. 12.8 % of national GDP)

77 % public

vs. 23 % private spending
(financing of the healthcare system)

1. Health care system in Austria

The Austrian health care system is characterised by the federal structure of the country. Through the multitude of decision-makers (federal government, states, municipalities, social insurance), health care financing is not regulated from one source, but rather depends on multiple sources of financing (i.a. taxes, social insurance premiums through social insurance, federal government, states, municipalities etc. – see chapter 1.3). This fragmentation makes an alignment between responsibilities essential. Important general conditions are therefore determined in mutual agreements and contracts (for example, agreements according to Art. 15a Austrian Constitutional Law – B-VG).

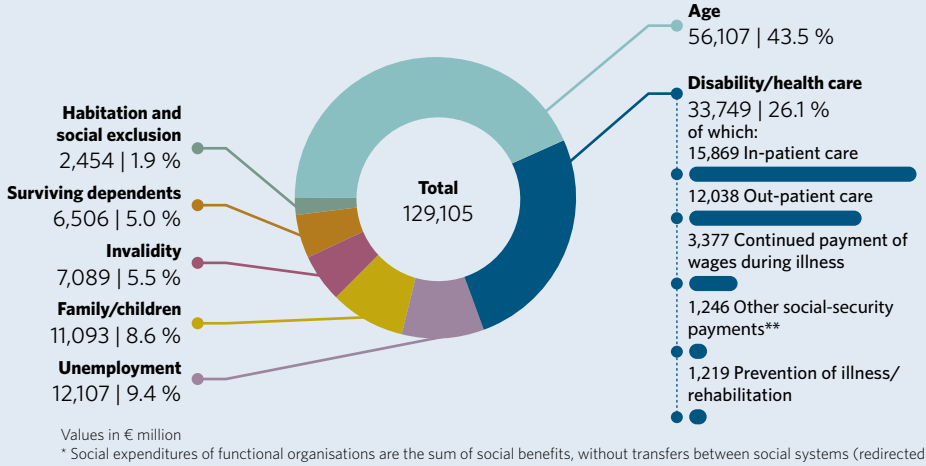
1.1 Basic economic information

The population of Austria in 2022 was 8,978,929 (see chapter 3). 99 % are covered by one of the five social insurance institutions (status 2022), in addition to 15 special health care institutions (see chapter 1.4).

1.2 Social expenditures

Social expenditures in total amounted to € 129.1 billion in 2021. Around two thirds of social expenses are allocated to retirement and health care benefits. The increase in spending compared to 2019 (+ 11.3 %) is attributable to those social benefits that were used more intensively or for the first time to cope with the social consequences of the COVID-19 pandemic (short-time work allowances, support payment for the self-employed, one-time payments to the unemployed and families, etc.).

Social expenditures* acc. to function in 2021



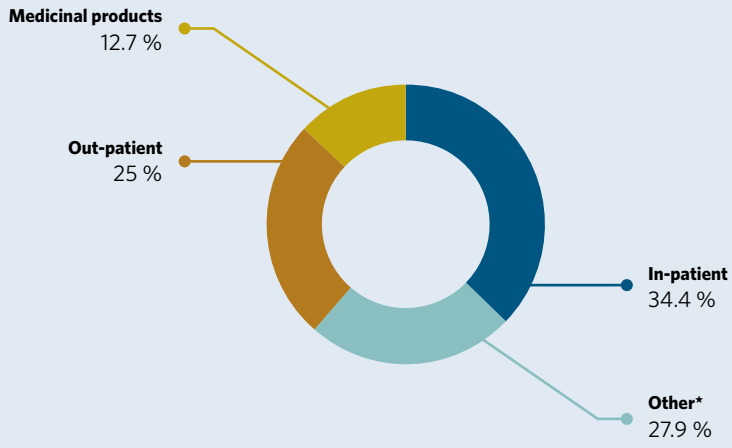
Values in € million
* Social expenditures of functional organisations are the sum of social benefits, without transfers between social systems (redirected social contributions and other transfers) and without other expenditures (administrative expenses, other not attributable expenditures).
** Other 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.

Source: Statistics Austria

1.3 Health care expenditures

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

In 2021, health care expenditures in Austria amounted to some € 52.1 billion, which corresponds to a share in GDP of 12.8 %.



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

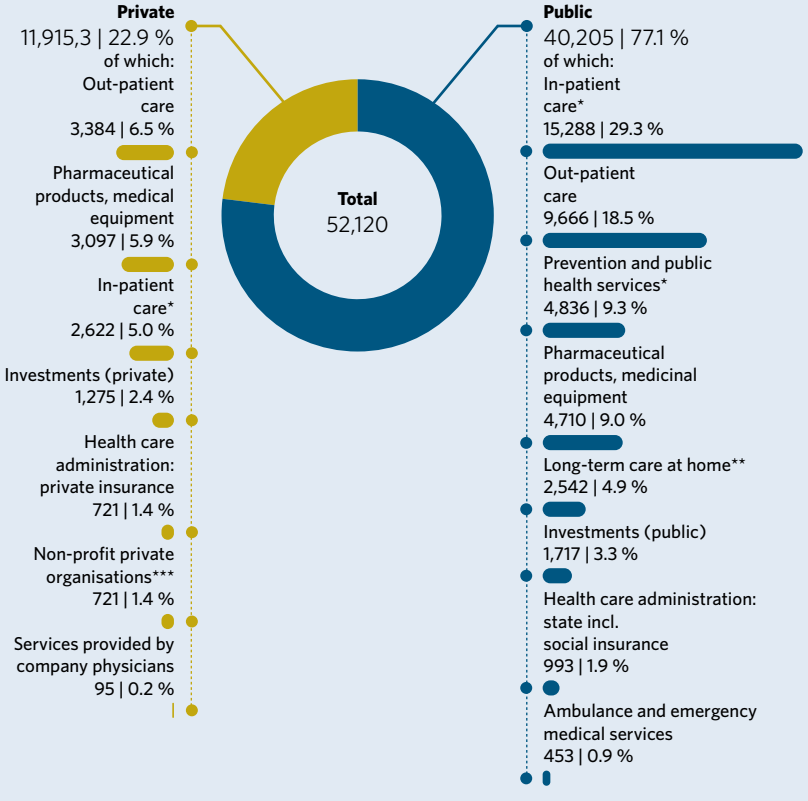
Source: calculated by the Institute of Pharmaeconomic Research (IPF) with reference to the following data: IQVIA, Statistics Austria, SV

The largest proportion of 34.4 % was spent on In-patient care. At the same time, expenditure on Out-patient care made up 25 % and expenditure on medicinal products amounted to 12.7 %.

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 health care settings (in-patient, out-patient, drug therapy) at national level.

Same as in 2020, spending on "Other" has risen sharply in 2021 (+27 % vs. 2019), which includes spending on long-term care, patient transport, public health services and preventive care, administration, medical equipment, and private insurance.
The significant increase in expenditure is attributable to pandemic-related expenses (such as testing, protective equipment, masks, logistics and transportation, contact tracing, treatment, vaccinations, etc.).

Health care financing 2021

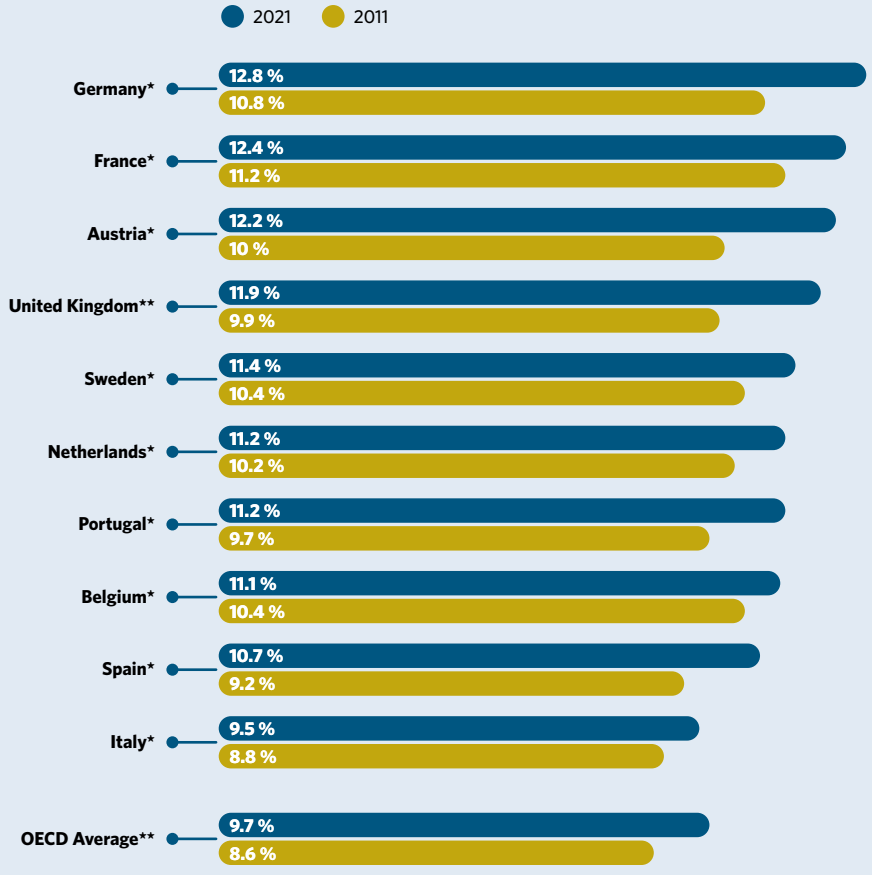


Values in € million | %
* Includes in-patient health care services in nursing homes.
** Public spending for long-term care at home also includes federal and provincial nursing allowances.
*** Includes information about the non-profit private organisations for rescue services and other health services.

Source: Statistics Austria

When broken down into public and private expenditure on health care, more than three fourths of the expenses are financed by public funds. The increase in spending compared to 2020 is primarily due to those services that were used to overcome the COVID-19 pandemic (expenses from preventive care).

Comparative health care expenditures – in % of GDP[1]



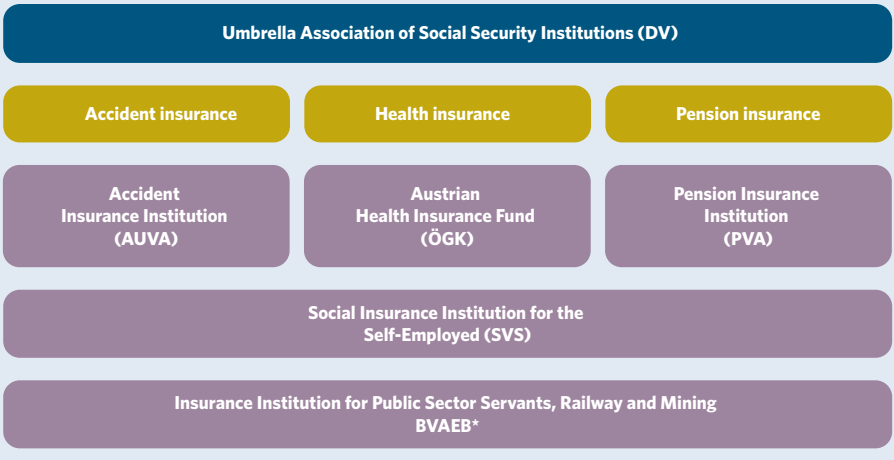
* provisional value
** from year 2020
1 graphical illustration of selected OECD countries

Source: Statistics Austria, OECD

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.

1.4 Social security system

The Austrian social security system



* incl. PV acc. Federal Pension Office Transfer Act

Source: SV

The current social security structure, consisting of five insurance institutions and the superordinate umbrella organisation, was introduced on 01.01.2020.

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

- **Health insurance**
- **Pension insurance**
- **Accident insurance**

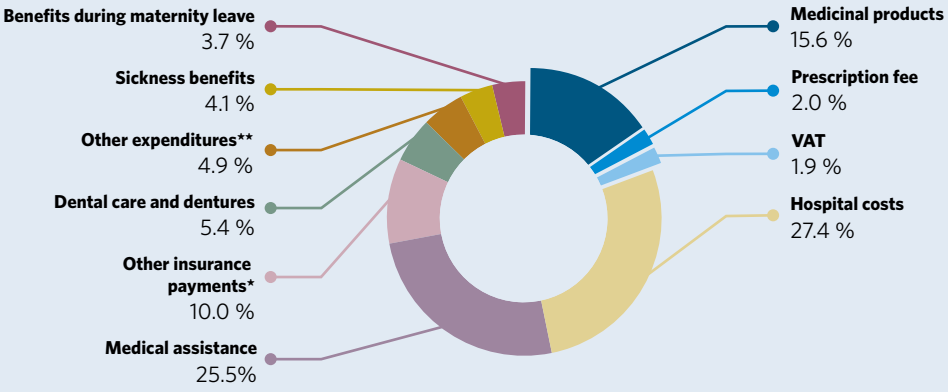
Membership is compulsory with the respective nationwide professional insurance company or the Austrian Health Insurance Fund (ÖGK [Österreichische Gesundheitskasse]). The statutory health insurance allows multiple insurances.

With 7.2 million insured persons (81 % of the people living in our country), the Austrian Health Insurance Fund is the largest social health insurer in Austria.

In addition to statutory health insurance, 15 health care institutions (KFA [Krankenfürsorgeanstalten]) provide health insurance for employees in various state and municipal administrations.

1.5 Social health insurance management

Health insurance



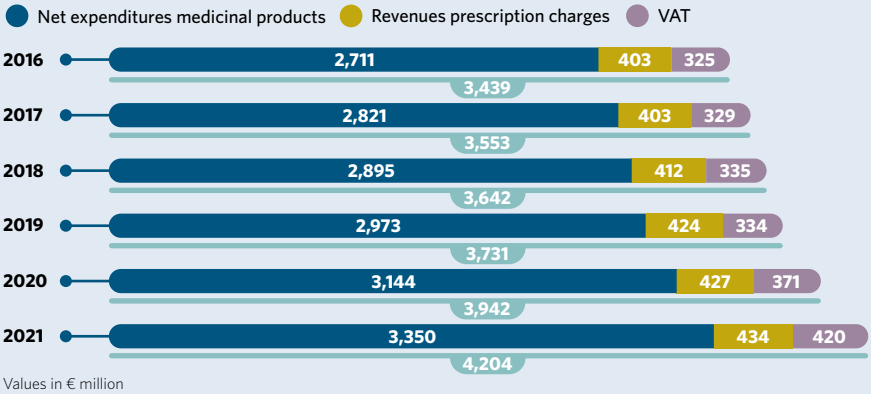
* Rehabilitation, medical aids, transport costs, disease prevention, early diagnosis, home nursing, health strengthening etc.
** Administration, remittance of equalisation funds, capital consumption, others

Source: SV

According to the final accounts, the revenues of the social health insurance institutions amounted to about € 21.4 billion in 2021 (+ 5.2 % vs. 2020), and the expenditures to € 21.5 billion (+ 5.6 %). The negative result amounted to minus € 118 million.

The expenditure positions for medicinal products (gross) include 10 % VAT and do not take received prescription fees into account. The net expenditure on medicinal products is further reduced by individual discounts and repayments by pharmaceutical companies to the social insurance (SV). These repayments substantially reduce the expenditure of the SV and lead to further reduction of the net expenditure of the SV. The number of repayments increases annually.

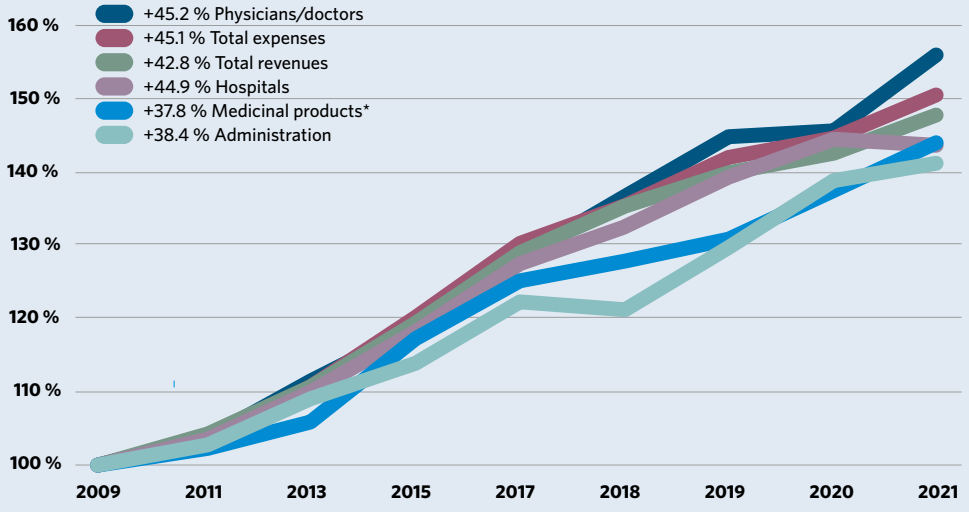
Expenditures for medicinal products



Values in € million

Source: SV

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

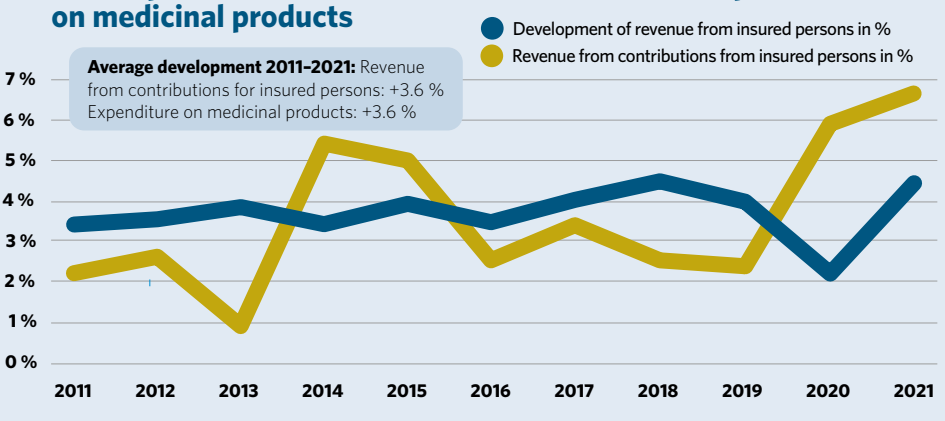


*Gross incl. prescription charges, VAT, refunds and discounts

Source: SV

In recent years, pharmaceutical expenditure has been the slowest growing area of the social security system.

Development of revenue from contributions vs. expenditure on medicinal products



Source: SV

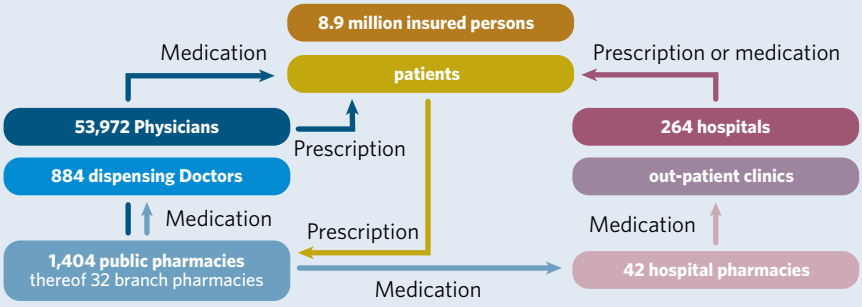
The revenue of the social health insurance institutions from contributions of all insured persons developed positively in the years 2011 to 2021 and increased on average by +3,6 %. Expenditure on therapeutic products grew by +3,6 % in the same period (prescription fees collected as well as individual discounts and reimbursements from pharmaceutical companies are not taken into account).

1.6 Health care structure and financing

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

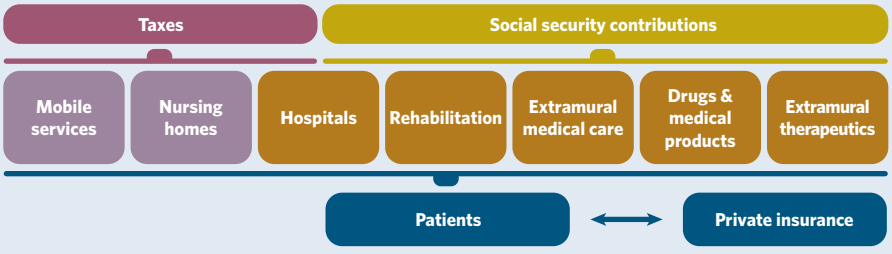
Physicians (general practitioners and specialists) **dispensing or non-dispensing** as well as **Primary Health Care Centers (PHC)**
- **hospitals and out-patient clinics**
- **public pharmacies**
- **other medical/therapeutic services**

Structure of Austria's health care system



Source: PHARMIG

Health care financing



Source: © BMSGPK

Financial equalisation

Financial equalisation regulates the financial relations between the federal government, the federal states, and the municipalities. The revenue from certain levies collected by the federal government is divided between the federal government, the federal states, and the municipalities. Financial equalisation is an agreement that must be negotiated and decided by mutual consent between the federal government, the federal states, and the municipalities. When financial equalisation is concluded, the tasks to be assumed and financed by each level are also agreed upon. In the light of the COVID-19 pandemic, the financial equalisation partners agreed to extend the financial equalisation scheme,

which was supposed to run out at the end of 2021, until the end of 2023. In 2023, the negotiations between the federal government, the states, and the social security system started for the new financial equalisation period.

Health target control

The aim of the partnership-based target control system for implementing the health care reform that has been underway since 2013 is to counteract the strong fragmentation of the health care system by joint and cross-sectoral control of the structure, organisation, and financing of health care. System partners consisting in federal government, federal states and social security conclude appropriate agreements in accordance with Article 15a B-VG [Bundes-Verfassungsgesetz, Austrian Federal Constitutional Law] on the health target control and on the organisation and financing of the health care system as well as contracts based thereon (currently 15a-VB 2017– 2023). The implementing body is the federal health agency.

Role-Model "Homogeneous access throughout Austria"

In October 2020, the decision-making body of the Federal Health Agency, the Bundes-Zielsteuerungskommission, decided on the coverage of costs for an innovative therapy approved for the first time by the European Medicines Agency (EMA) by a **fund established at the federal level. Based on an expert-supported decision, treatment centres were defined,** that fulfil the necessary structural criteria for a qualitatively assured implementation of this therapy as well as the associated pre- and post-treatment care.

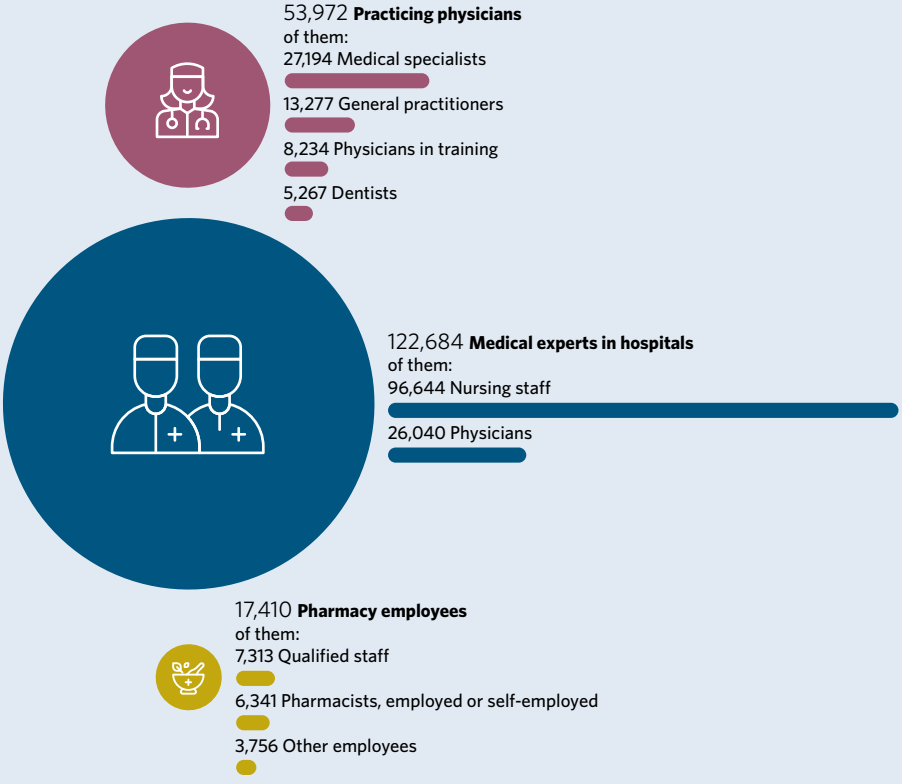
With the decision by the Bundes-Zielsteuerungskommission it was ensured that the Federal Health Care Agency would meet the costs for the implementation of a newly EMA-approved drug therapy for children with spinal muscular atrophy (SMA) under clearly defined indications and conditions and at precisely specified service centres with appropriate expertise in Austria. This means that this cost-intensive therapy is available to all insured patients, regardless of their place of residence, at all agreed service locations in Austria. A major concern of the financiers was also to link the financing of this novel therapy with a verifiable sustainable treatment success and to monitor this treatment success scientifically over several years. As of the end of 2021, it was agreed by the Bundes-Zielsteuerungskommission that the Federal Health Agency would provide nationwide funding, again under very clearly defined conditions, for another cost-intensive drug therapy (voretigene neparvovec [LuxturnaTM]), which has been approved in the EU for the treatment of retinal dystrophies in individuals with biallelic mutations in the RPE65 gene. These pioneering pilot projects – if they prove successful – will certainly be followed by other promising models.

Source: BMSGPK Sektion VII/B, Mag. Gerhard Embacher, 2022

1.7 Employees In the health care system

In 2021, Austria's 8.9 million inhabitants were supplied by 1,404 public pharmacies (with 32 branches), 42 hospital pharmacies and 884 dispensing doctors (who dispense medicines directly to patients).

Employees in the health care system in 2021



Source: Statistics Austria, Austrian Chamber of Pharmacists

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2021: 264 hospitals

153 acute short-term care

111 non-acute care

7.1 beds

per 1,000 inhabitants = 2nd place

in international comparison

2. Hospitals in Austria

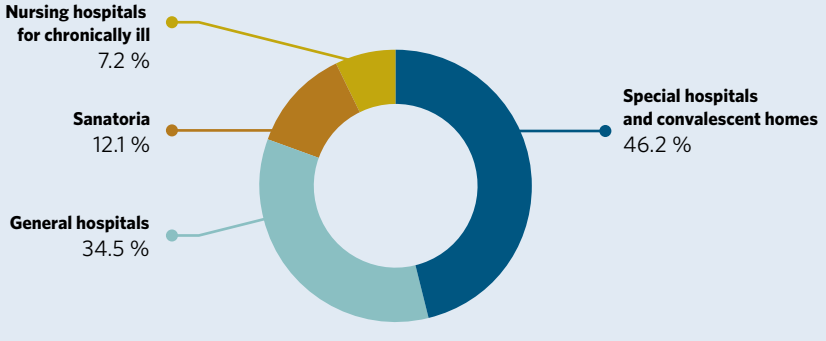
In Austria, hospitals totalled 264 at the end of 2021. The hospital system is of federal nature, i.e. the jurisdiction is with the provincial governments. The legal basis for all hospitals is the Federal Hospitals Act (KAKuG). This act serves as the basis for the 9 provincial acts.

Hospitals are financed from multiple sources, mainly from taxes and lump-sum contributions from social security providers of hospital financing as well as by the federal states, and the federal government. In addition, patients make small co-payments ("daily allowance"), see chapter 2.2. Hospital funding.

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.
- **Convalescent homes:** for people who require 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) 2021



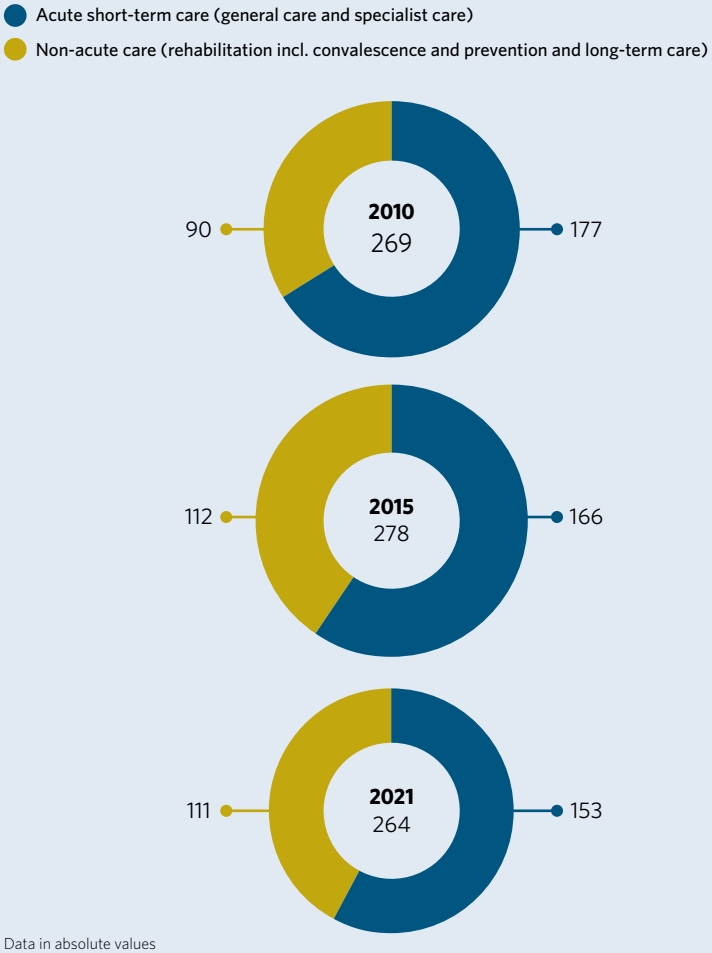
Source: Statistics Austria, BMSGPK

2.1 Structural details of hospitals

Of these 264 hospitals, 110 (42 %) are hospitals with public status and 154 (58 %) without public status. Hospitals with public status are not to be confused with hospitals of public agencies and institutions.

In 2021, 153 hospitals were available for acute short-term care (regular and special care) and 111 for non-acute care (rehabilitation incl. recovery, preventative care, long-term care).

Development of hospitals according to care function

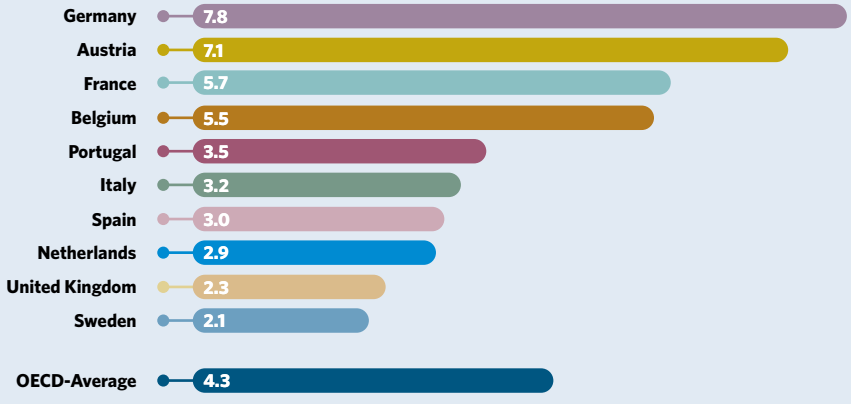


Data in absolute values

Source: BMSGPK

Throughout the years, the number of institutions in the area of acute short-term care has decreased from 177 (2010) to 153 institutions (2021). In comparison to this, the area of non-acute care has increased from 90 institutions (2010) to 111 (2021).

Hospital care in international comparison 2021*



Hospital bed capacity per 1,000 inhabitants
*Graphic representation of selected OECD countries for 2021 or 2020

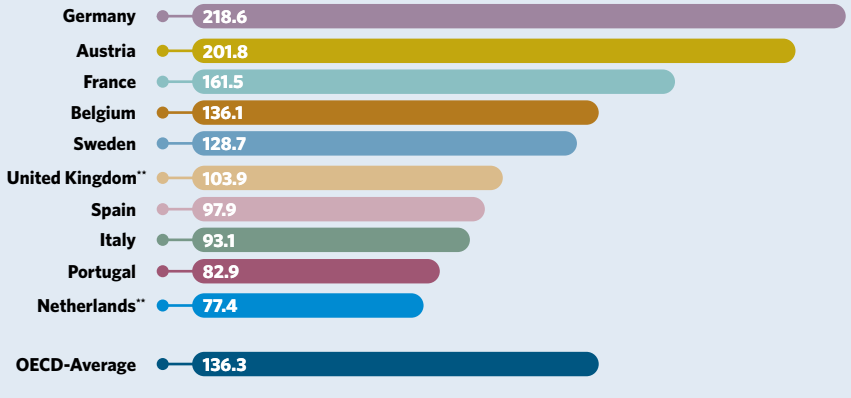
Source: OECD, Health at a Glance 2022

With 7.1 beds per 1,000 inhabitants, Austria is in second place behind Germany (7.8 beds) in the 2021 OECD country comparison.

Austria has 65 % more hospital beds than the average of the OECD countries. There is a slight decline compared to 2008 (7.7 beds per 1,000 inhabitants).

Along with the large availability of hospital beds Austria also has the second highest number of hospital treatments per number of inhabitants after Germany compared to other European countries (202 vs. OECD-Average: 136).

Hospital discharges in 2021*



Hospital discharges per 1,000 inhabitants
* Graphic representation of selected EU countries for 2021 or 2020
** excluding rehabilitative care, long-term care and palliative care

Source: OECD, Health at a Glance Europe 2022

Development of bed capacity in Austria

The overview also indicates the actual number of beds in Austria's hospitals in 2021 (61,927). In relation to Austria's population, the bed coverage was 6.92 beds per 1,000 inhabitants.

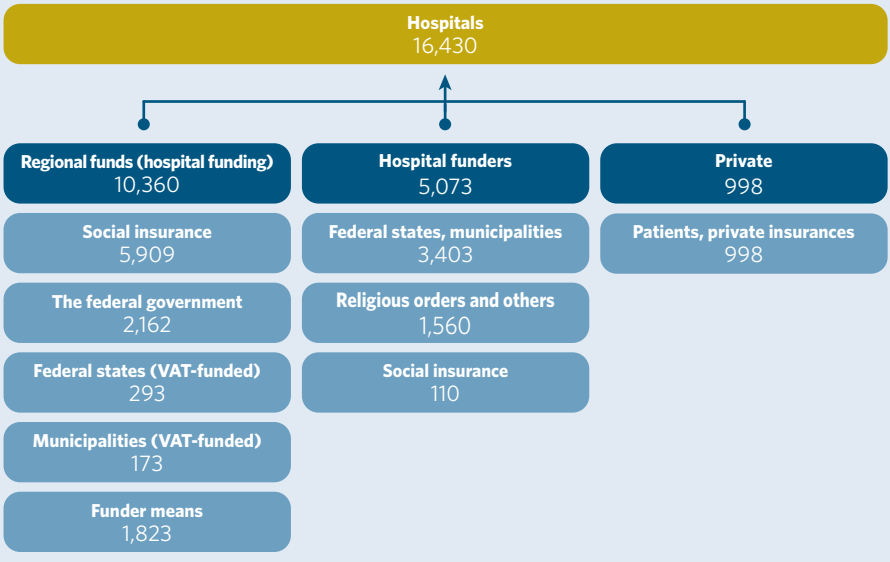
- **In 2021, 2.1 million hospitalisations for in-patient treatment were reported in Austrian hospitals.**
- **The hospitalisation frequency** (= hospital stays per 100 inhabitants) **amounted to 24.8 %** (2010: 33.4 %, 2020: 23.7 %).
- **The average duration in acute care hospitals in 2021 is 6.3 days** (full hospital stays in acute care).

Due to the pandemic, the number of hospital discharges from acute care hospitals has decreased significantly in the last two years.

2.2 Hospital funding

The expenditure of Austrian hospitals operating on the "LKF" basis (system of performance-oriented hospital financing) amounted to € 16.4 billion in 2021. Of these, more than 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.

Payments for funded hospitals in 2021



Values in € million

* 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 in-patient care, payments to the remaining hospitals (funds for private hospitals, emergency hospitals, etc.) and payments for hospitals abroad. It does not include expenses for out-patient care. These expenses are recognised as medical attention and equivalent services (out-patient services in hospitals).

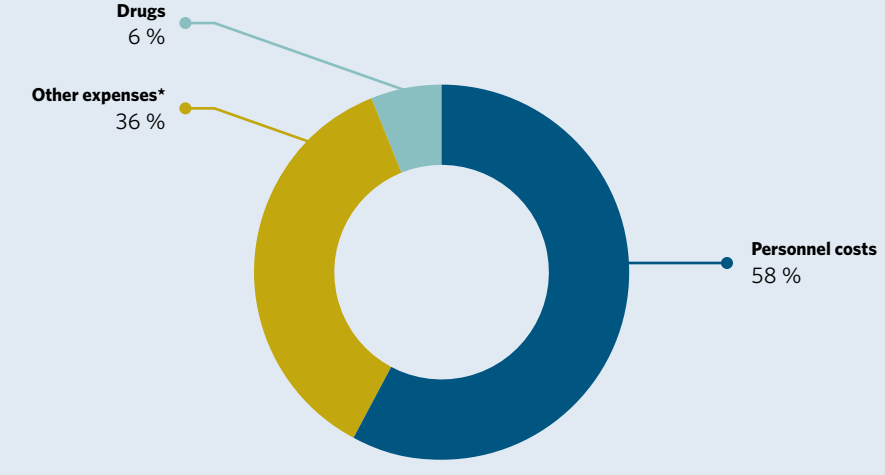
Source: calculated by the Institute for Pharmaeconomic Research (IPF) with reference to the following data: SV, BMGF/BMSGPK, Statistics Austria

Social insurance makes a large contribution of the hospital funding. Of € 10.36 billion which are financed by regional health insurance funds, almost 60 % are covered for by the social insurance system.

Hospitals financed by regional health funds

The total costs of the hospitals financed by the regional health funds (109 hospitals with 41,577 beds) amounts to € 16.4 billion and concern the inpatient and outpatient sector. More than 50 % of the costs are accounted for by personnel, about 6 % by drugs and 36 % by other expenses.

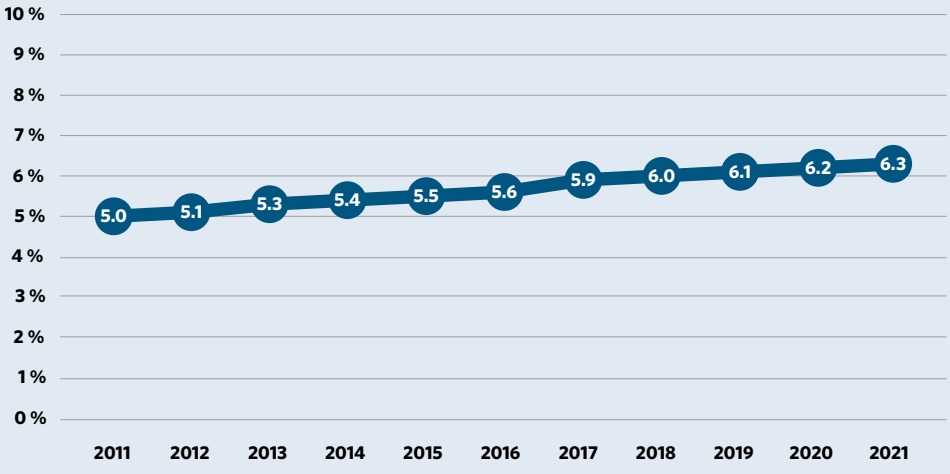
Costs in hospitals 2021



*Catering, training etc.

Source: On the basis of statutory provisions (Cost Accounting Ordinance, BGBl. [Federal Law Gazette] II Nr. 638/2003 in the version of BGBl. II Nr. 18/2007), the costs of hospitals financed from public funds via the 9 state health funds are collected.

Development of drug costs



Values in %

Source: On the basis of statutory provisions (Cost Accounting Ordinance, BGBl. [Federal Law Gazette] II Nr. 638/2003 in the version of BGBl. II Nr. 18/2007), the costs of hospitals financed from public funds via the 9 state health funds are collected.

The development of drug costs has remained constant at 5 to 6 % over the past 10 years.

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8.9 million people

lived in Austria at the beginning of 2022

From the age of 50,

the need for medicines increases

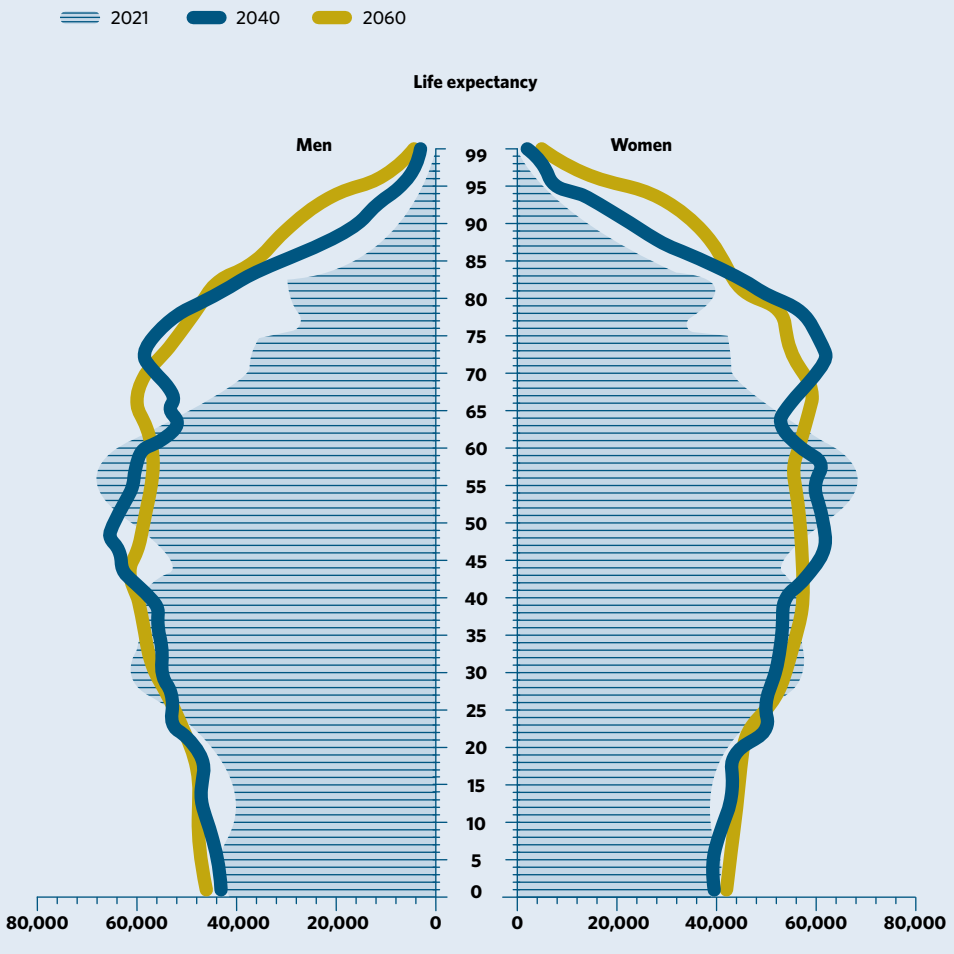
Two thirds

of all deaths are caused by cardiovascular diseases and cancer

3. Population structure and demographic trends

3.1 Population structure

Population pyramid 2021, 2040 and 2060



Source: Statistics Austria, 2022

According to Statistics Austria, at the beginning of 2022, 8,978,929 people were living in Austria. By the end of 2022, an increase of +1.4 % was recorded. Based on preliminary results, the 9 million mark has already been reached. Strong population growth is forecasted until 2060 and a further shift in the age structure towards higher ages. The expected population growth is primarily attributable to migration gains (including immigration as a result of the Ukraine war). According to the forecast, around 9.65 million people will live in Austria by 2040.

Life expectancy has increased in recent decades and is 78.8 years for men (at birth in 2021) and 83.7 years for women. However, due to COVID-19 life expectancy in 2020 and 2021 has decreased compared to previous years.

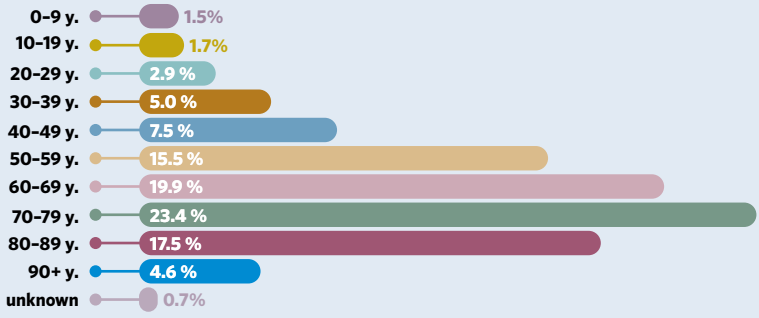
Share of age groups in total population

In 2021, people over the age of 65 accounted for approximately 19 % of the total population, while around the same number of children and young adults under the age of 20 lived in Austria. Only 1.0 % of the population reached the age of 90 or more. The age group between 20 and 64 is the most common, accounting for approximately 61 %. With a share of approximately 16.0 %, the 50- to 60-year-old represent the largest age group.

3.2 Need for medicinal products by age group

The need for medicinal products in %

(health insurance patients, by units)

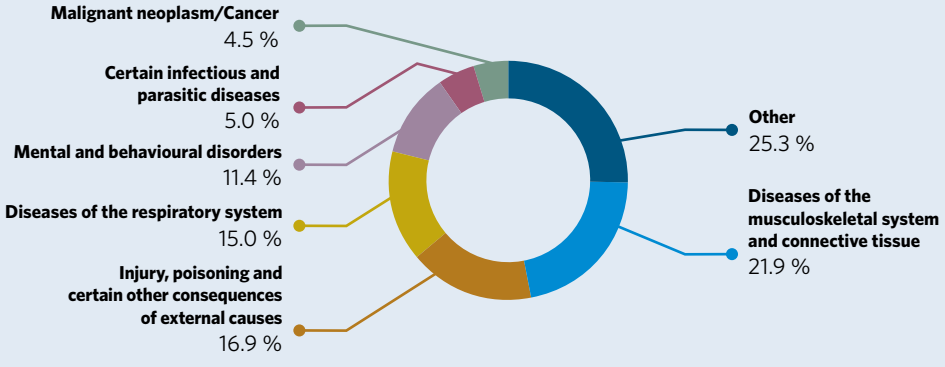


Source: Austrian Chamber of Pharmacists, 2020

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 50.

3.3 Frequent causes of illness

Illness groups as percentage of sick leave days



Survey group: blue collar and white collar | Values in %

Source: Statistics Austria, 2022

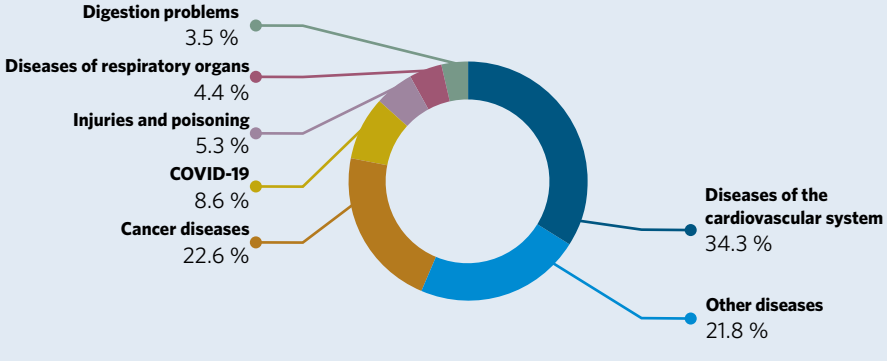
The 4,197,542 cases of illnesses causing absence from work and the 43,039,853 days of employee absence in 2021 show that illnesses of the musculoskeletal system and of the respiratory system are the main causes for notifications of sickness.

Diseases of the musculoskeletal system together with diseases of the respiratory system represent the cause for approximately 37 % of the notifications of illness.

3.4 Mortality

The two most frequent causes of death – cardiovascular diseases and cancer – cause almost two thirds of all deaths.

Mortality by causes of death



Values in %

Source: Statistics Austria, 2022

In line with the increase in life expectancy (see chapter 3.1) mortality for both sexes has decreased by 8 % over the past 10 years (2019 vs. 2010), although the mortality risk for men remains significantly higher for the two most common causes of death. In 2020 and 2021 nearly 10 % more deaths were recorded than in 2019. The increase was primarily due to the COVID-19 pandemic.

Classification of ICD-10:

- **Diseases of the cardiovascular system:** heart attack, stroke, hypertension etc.
- **Malignant neoplasm:** cancer (lungs, stomach, breast, prostate, blood)
- **Other diseases:** nutritional and metabolic diseases (Diabetes Mellitus), virus infections (HIV), psychiatric diseases, diseases of the nervous system, kidney, congenital malformations etc.

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3.2 %

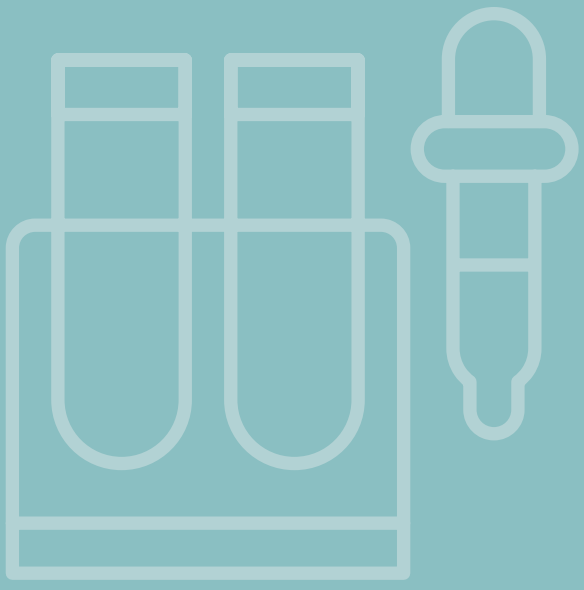
research ratio in 2022

278 clinical trials

were applied for on average per year in Austria in the last 5 years

206 new drugs

in the last 10 years in Austria,
thereof 54 in 2022



4. Pharmaceutical research, development and production

Research location Austria

In the comparative assessment of research and innovation performance of the EU member states, Austria ranks – as in the previous year – 8th in 2021 and in the "European Innovation Scoreboard", which is published annually by the European Union, Austria is classified again as a "strong innovator". Compared to 2015, this represents a significant improvement of +4.6 %. Austria thus ranks behind Ireland and Luxembourg and other strong innovators (like Germany, Cyprus and France) with its innovation performance above the EU average. The innovation leaders are Sweden, Finland, Denmark, the Netherlands and Belgium, whose innovation performance is far above the EU average.

The share of expenditure on research and development (R&D) in gross domestic product (GDP), expressed as a percentage, is referred to as the research ratio. This was 3.17 % in 2021, which was above the European target of 3 %, and has increased steadily over the last 10 years (2012: 2.91 %).

For 2022, a research ratio of 3.26 % is expected. This means an increase of +0.03 % compared to 2021 (according to calculations by Statistics Austria from April 2023; The global estimate includes the drop in economic performance for 2020 and 2021).

- **With 50 % the largest share of the total research expenditure** (amounting to almost € 13 billion in 2021) **is borne by companies**
- **33 % was borne by the public sector**
- **16 % by foreign countries.**

With research contracts the pharmaceutical industry in particular contributes to the value added in Austria: In 2019, Austrian companies in the pharmaceutical industry invested € 283 million for research and development (Statistics Austria 2019).

4.1 Active substances

As soon as a new active substance candidate has been identified, it is developed further on a broad scientific basis. 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 molar mass of no more than 1,000 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 9.5) are copies of originator products that contain the same active ingredient in the same quantity as the original. They can be offered in the market once the patent of the original expires and may be approved in a "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 9.6) 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 molar mass of several 1,000 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, etc.). 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.

4.2 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

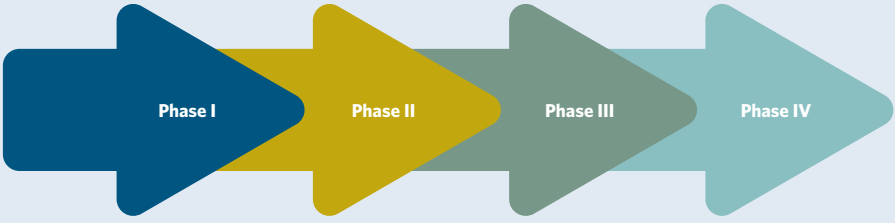
Within the EU, uniform administrative rules for clinical trials have been established since Jan. 31, 2022, under **EU Regulation 536/2014 on clinical trials and medicinal products for human use.** As of Jan. 31, 2023, new applications for approval can only be submitted in accordance with this new regulation and via the **Clinical Trials Information System (CTIS),** which was established for this purpose. Clinical trials still running under Regulation 2001/20/EC have a three-year transition period. Within this transition period – until Jan. 31, 2025 - clinical trials must be completed or converted to the requirements of Regulation EU 536/2014. The national requirements are regulated in the Austrian Products Act in §2a and §28 to §48. An overview of the legal requirements as well as recommendations can be found on the following BASG website: www.basg.gv.at

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 cannot always be provided and is therefore not mandatory. Only when an active substance concluded all preclinical tests positively 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, to ease the suffering of many patients and provide hope in cases of severe illness. 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 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: Documentation of a biological signal to prove efficacy and to determine the best possible therapeutic dose. Furthermore, information on tolerability and possible interactions is to be collected. The collective of patients with the relevant disease to be examined in this phase is between 50 and 200 people.

The trials are usually controlled, i.e. involving a control group and are double-blind trials (neither the doctor nor the patient knows whether the active substance or the control substance is being administered). This is to avoid a possible influence on the treatment result.

Phase III: Establishing the therapeutic efficacy

Unlike the previous phases, the trial in phase III is carried out on a large number of patients (with the relevant disease). The size of the patient group is determined depending on the indication 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 multicentre trials are conducted in several countries at the same time (multinational) 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.

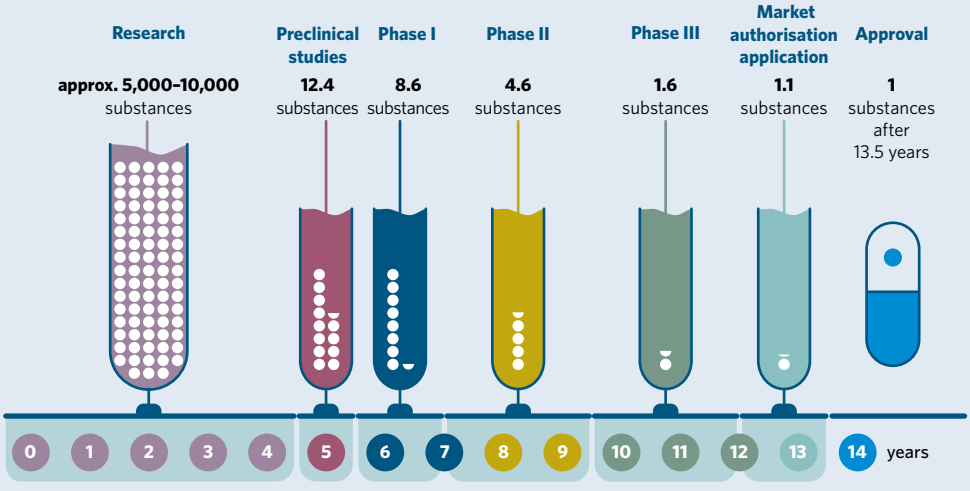
Non-interventional study (NIS)

With the EU Regulation on clinical trials with medicines for human use (Regulation (EU) No. 536/2014) taking effect on Jan 31, 2022, NIS is defined as a "clinical study that is not a clinical trial". A NIS is suited for proving the efficacy of a medicinal product in practice and for documenting side effects which have not occurred in clinical trials due to limited numbers. In doing so, the boundary of clinical trial must not be crossed. The decision to prescribe the drug must not be made together with the decision to enrol the participants in the non-interventional study. Furthermore, no diagnostic procedures or monitoring procedures beyond normal clinical practice may be used. This ensures that the treatment corresponds to the "real world setting", meaning with regular clinical daily routine.

BMSGPK and BASG have published a new guideline on the distinction from other studies and the "PHARMIG Guideline on Quality and Transparency of Non-Interventional Studies" has also been updated:
BMSGPK und BASG Leitfaden zur Abgrenzung klinische Studie – Nicht-Interventionelle Studie – sonstige Studie
PHARMIG Leitlinie zu Qualität und Transparenz von Nicht-Interventionellen Studien

A compulsory registration for NIS in the sense of §2a (3) of the Medicinal Products Act or of Article 2, Paragraph 2 Z4 of the Regulation (EU) 536/2014 no longer exists. The previous regulation on the compulsory registration for NIS was rescinded on Oct. 07, 2022.

Development phases of a medicinal product



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

Development costs

Drug developing is a high-risk process: on average, only one in between 5,000 to 10,000 initial substances is actually approved in the end. According to recent studies, the average cost of developing new, innovative medication is up to US$ 2.6 billion (DiMasi et al. 2016). These costs include the direct costs for developing the medication, the associated failures and the opportunity costs; i.e. the indirect costs of financing such long and cost-intensive development projects. These high costs arise from the documentation and safety requirements for clinical trials and the large number of trial participants required. 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

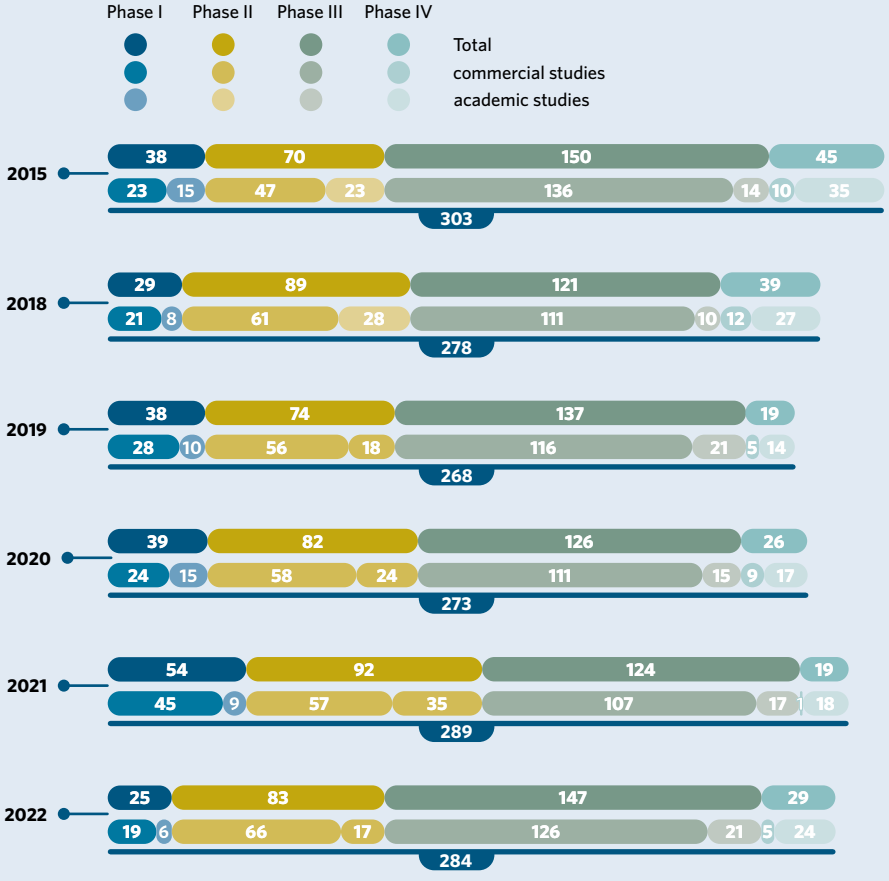
Clinical trials in Austria – a statistical overview

The number of first-time applications for clinical trials in Austria has decreased slightly compared to the previous year. Overall, the number of clinical trials in Austria has been very stable over the last five years, but at a rather low level. On average in the EU, about 80 % of clinical trials are conducted by the pharmaceutical industry (industry-sponsored); 20 % by academic scientists (academically sponsored). With a share of 23.9 %, Austria is slightly above this figure.

In regard to academic studies, a decline of more than 10 % compared to the previous year can be seen. One possible explanation is that commercial and academic studies have been subject to the same fees since 2022. On top of that, since Jan. 31, 2023, clinical trials can only be submitted in accordance with Regulation (EU) 536/2014 ("Clinical Trials Regulation" or "CTR") and thus in the Clinical Trials Information System (CTIS). Due to the formal and technical requirements, academic sponsors may have insufficiently used this new CTIS reporting system.

The slight increase in multinational studies can be explained by the resulting increase in commercial – often multinational – studies with a simultaneous decrease in academic – mostly national – studies.

Distribution of clinical trial applications in Austria according to the phases



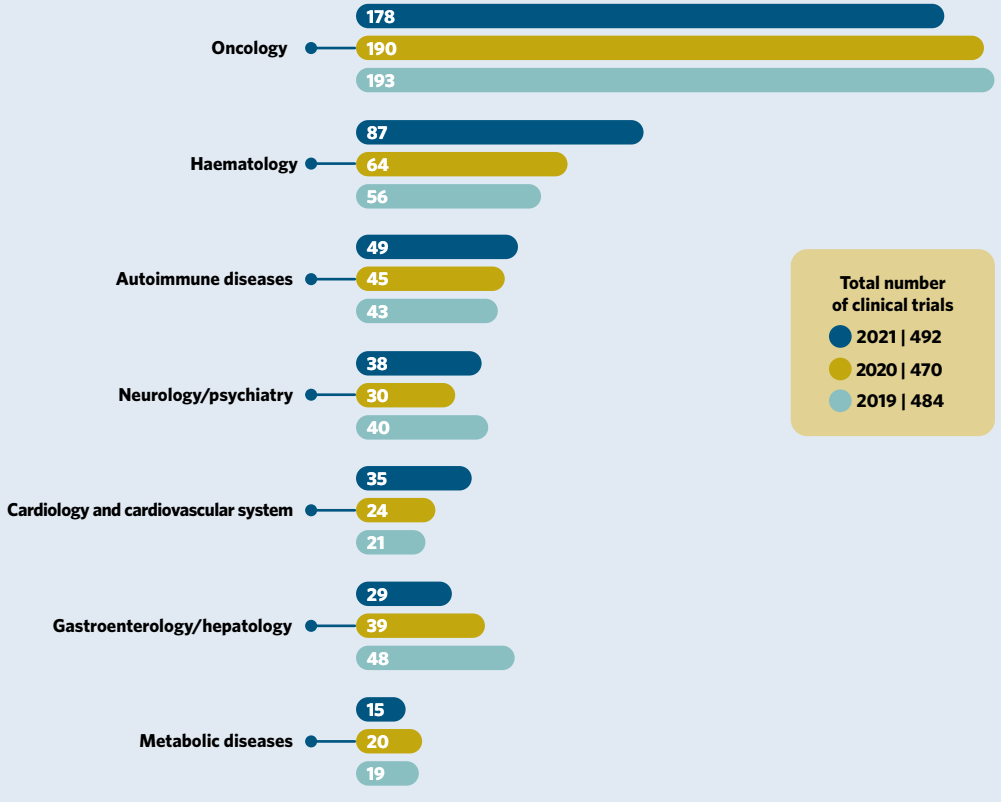
Data in absolute values

Source: BASG

Industry-sponsored clinical research in Austria

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 participated in these trials give us an overview of the services of the pharmaceutical industry. PHARMIG carries out an annual survey among the member companies on industry-sponsored clinical research in Austria. Around 32 companies participated in the survey during the past five years retrospectively. This corresponds to a market coverage of approximately 79 % (in terms of revenues as of all PHARMIG member companies). In 2022, the survey was revised; the number of non-interventional studies was no longer inquired, instead the distribution of clinical trials per state was surveyed.

Number of clinical trials from 2019–2021 according to the most researched indications

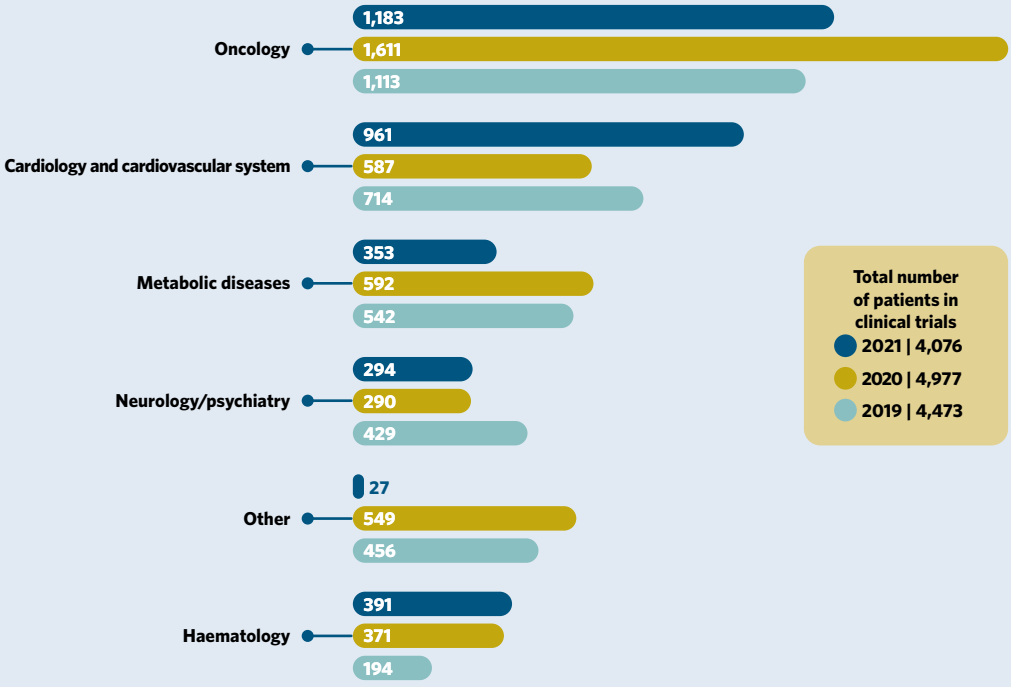


Data in absolute values

Source: Survey on industry-sponsored clinical research in Austria, PHARMIG 2019-2021

The **average total** of approximately **482 clinical trials** per year over the last three years includes ongoing, initiated and terminated clinical trials.

Number of participants in clinical trials according to the most researched indications*

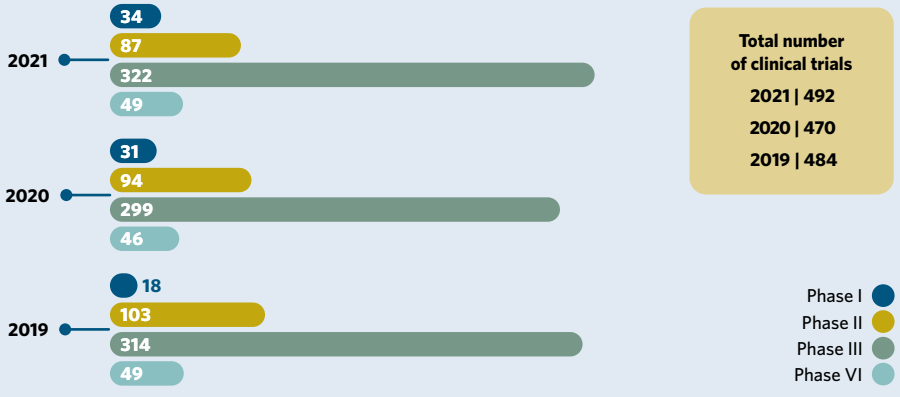


*Information on the number of patients is available for an average of 77 % of clinical trials | Data in absolute values

Source: Survey of industry-sponsored clinical research in Austria, PHARMIG 2019-2021

Around 4,508 patients participated in ongoing, initiated and terminated clinical trials in Austria over the last three years.*

Number of running clinical trials according to phases in AT 2019–2021

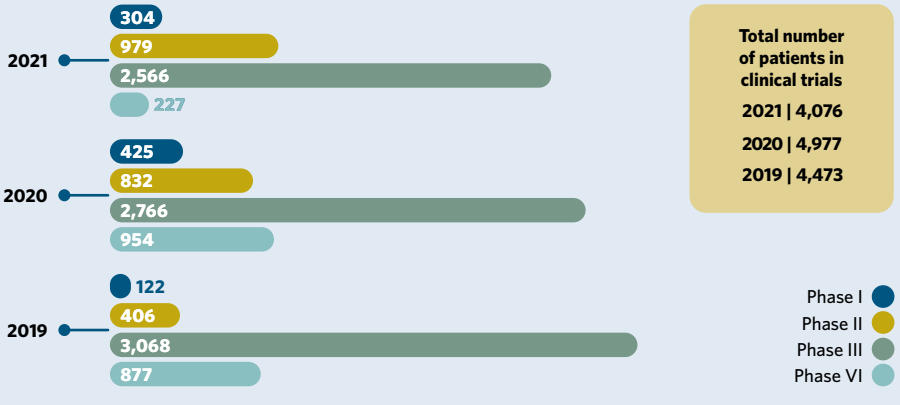


Numbers in absolute

Source: Survey on industry-sponsored clinical research in Austria, PHARMIG 2019-2021

Furthermore, through the support of the pharmaceutical industry, on average 133 "investigator initiated trials" were made possible per year in the years 2019–2021.

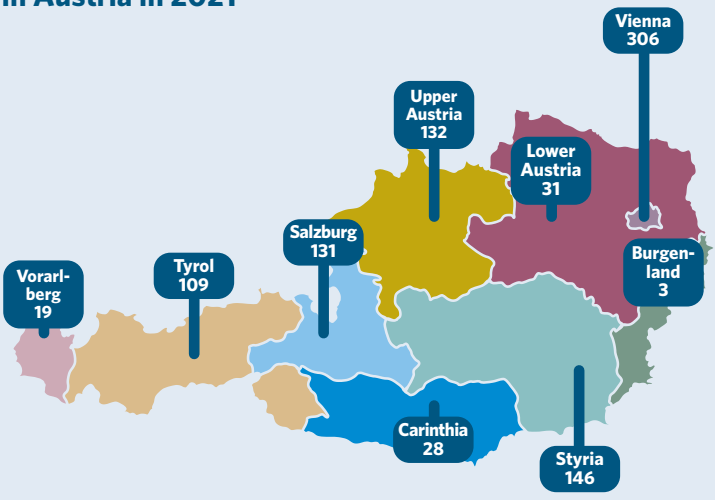
Distribution of patients in ongoing clinical trials according to phases*



*Information on the number of patients is available for an average of 77 % of clinical trials | Data in absolute values

Source: Survey on industry-sponsored clinical research in Austria, PHARMIG 2021

Distribution of ongoing clinical trials according to state in Austria in 2021*



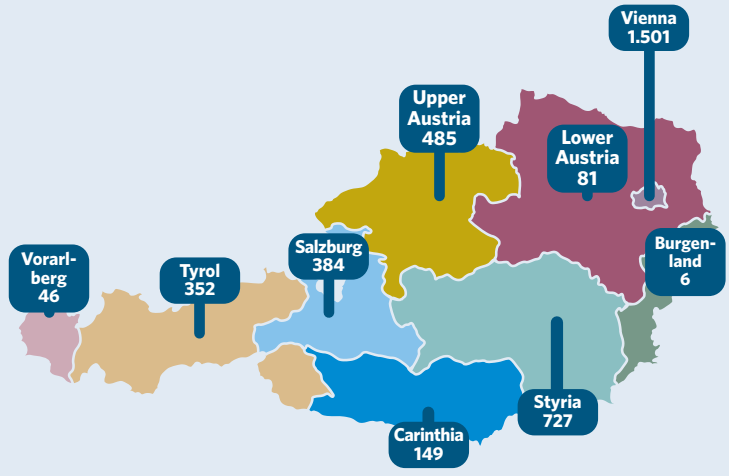
*Data provided for 76 % of clinical trials. | Data in absolute values
Most ongoing clinical trials in Austria are multinational and multicentre, i.e., a clinical trial can run in two or more provinces or centres.

Source: Survey on industry-sponsored clinical research in Austria, PHARMIG 2019-2021

	Vienna	Lower Austria	Upper Austria	Styria	Tyrol	Carinthia	Salzburg	Vorarlberg	Burgen-land
Population absolute values	1,973,403	1,717,617	1,521,843	1,264,384	769,613	568,946	568,317	405,542	301,203
	22 %	19 %	17 %	14 %	8 %	6 %	6 %	4 %	3 %

Source: Statistics Austria 2022

Average number of participants in ongoing clinical trials according to state in Austria in 2021*



*Data provided for 62 % of clinical trials. | Data in absolute values

Source: Survey on industry-sponsored clinical research in Austria, PHARMIG 2021

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 sufficient supply of children with medicinal products which have been adequately studied and authorised for use in children is essential and has therefore been required by EU regulation since 2007.

All new marketing authorisations, 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.

OKIDS – Child Research Network

OKIDS is a public-private partnership acting as a network for promoting paediatric studies in Austria (okids-net.at). It serves as a central contact point for sponsors of all important stakeholders in paediatric research (pharmaceutical industry, university medical centres, clinical trial coordination centres, specialty departments, etc.). Together with the Federal Ministry of Health and funds from the "joint health care objectives from the pharmaceutical framework agreement", 30 companies have been supporting OKIDS since 2013 with core funding for 5 years.

After the successful inclusion in the European paediatric research network Enpr-EMA (European Network of Paediatric Research at the European Medicines Agency) and as a project partner of PedCRIN (Paediatric Clinical Research Infrastructure Network – project has been completed) and c4c (Connect for Children), OKIDS has taken on important tasks in European structural planning and is, thus, gaining increasing visibility in the European study landscape for paediatric medicines. OKIDS was part of the Enpr-EMA working group on "Trial Preparedness" with a focus on establishing early synergies and cooperation between industry and academic partners in drug development.

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: www.clinicaltrials.gov
- In the European Clinical Trials Register (EudraCT) operated by the **European Medicines Agency** (EMA), clinical trial data from the EU, Iceland, Liechtenstein and Norway have been made accessible since 2011, which were carried out on the basis of the EU Directive 2001/20/EC or are still being carried out until Jan. 31, 2025: www.clinicaltrialsregister.eu
- **Information on clinical trials** that have been conducted since Jan. 31, 2021 in accordance with the EU regulation on clinical trials on medicinal products for human use (Regulation (EU) No. 536/2014) is published on the following website: www.euclinicaltrials.eu

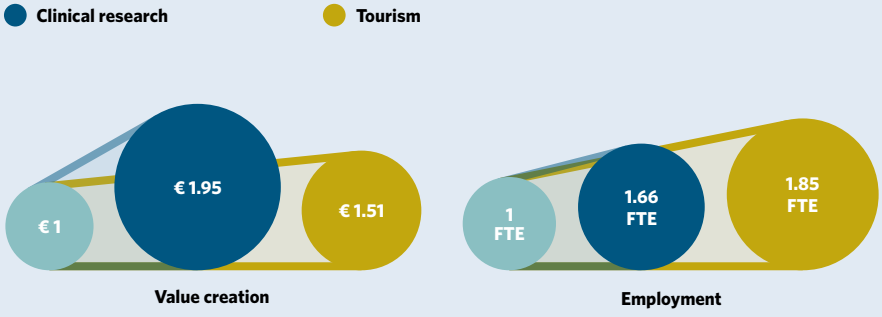
- **Non-Interventional Studies** which have been commissioned by authorities and which are conducted in several EU member states, so-called PASS (Post Authorisation Safety Studies), must be reported to the EU PASS register of EMA: www.encepp.eu
- **Full access to clinical trial data has, on the basis of the "EMA policy 0070 on publication of clinical data"**, been made possible by EMA's centralised approval procedure as of Jan. 01, 2015. Upon completion of the first implementation phase, interested parties can access clinical reports by means of a registration process on the EMA website: clinicaldata.ema.europa.eu
- **Many companies have voluntarily committed to support** the responsible use of clinical trial data and also enable full access to their study data. A summary of the principles of this voluntary commitment can be found here: www.efpia.eu

The value creation of industry-sponsored clinical trials

The value creation generated by conducting industry-sponsored clinical trials in Austria amounts to € 144.2 million annually. Each year, a medical treatment value of € 100 million was financed through 463 industry-sponsored clinical trials with an average medical treatment value of € 37,068 per recruited patient. This treatment value includes free trial medication, the assumption of costs for diagnostics, therapy as well as administrative services and documentation. This corresponds to a significant share of 0.3 % of the current annual health expenditure.

Every euro invested in clinical trials by the pharmaceutical industry generates € 1.95 for the Austrian economy. Jobs in the order of 2,021 full-time equivalents are created and secured, which leads to an employment multiplier of 1.66 (see chapter 8.3).

Industry-sponsored clinical trials



Source: Study of the Institute for Pharmaeconomic Research (IPF) in cooperation with PHARMIG from 2019, published in the Journal of Medical Economics: www.ncbi.nlm.nih.gov/pubmed/32046538

The overall economic benefit of € 144.2 million annually is divided into direct (gross production value), indirect (advance performance relationship of the suppliers of clinical trials) and secondary (consumption and investment effect in other economic areas) effects.

Effects	Value creation	Employment
Direct effects	€ 74.13 million	1,215 FTEs
Indirect effects	€ 38.47 million	475 FTEs
Secondary effects	€ 31.60 million	331 FTEs
Total	**€ 144.19 million**	**2,021 FTEs**
Multiplier	€ 1.95	1.66

Source: Study of the Institute for Pharmaeconomic Research (IPF) in cooperation with PHARMIG from 2019, published in the Journal of Medical Economics: www.ncbi.nlm.nih.gov/pubmed/32046538

The performance of clinical trials by the pharmaceutical industry leads – in addition to the benefit for patients – to positive macroeconomic effects (contributions to the Austrian health care system, but also location and industrial policy).

4.3 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 authorisation by authority which requires dedicated and sufficient space, technical equipment and facilities for quality control. In the European Union a Qualified Person (QP) must 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 with 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
- Supplier qualification
- In process controls
- Validation
- Quality control
- Deviation management
- Change management (change control)
- Complaints and recall

National and international regulations

GGMP 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 consumer.

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

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

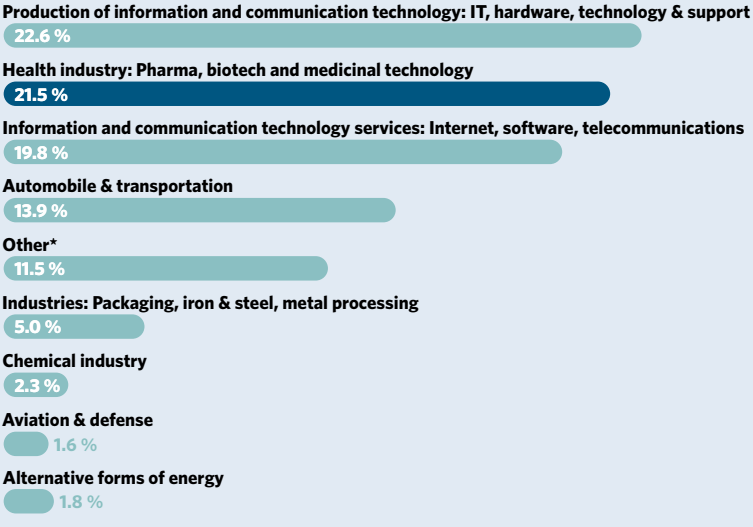
Measures against falsified medication

Security features on every pack of medication should make any tampering immediately apparent and ensure the medication is fully traceable from the manufacturer to the pharmacy (see chapter 6.2).

4.4 Research and development – investments

The health care industry (biotechnology, health care providers, medical technology, and medicinal products) is globally responsible for about a fifth of research and development expenditures.

Research rate, by industry (Europe)



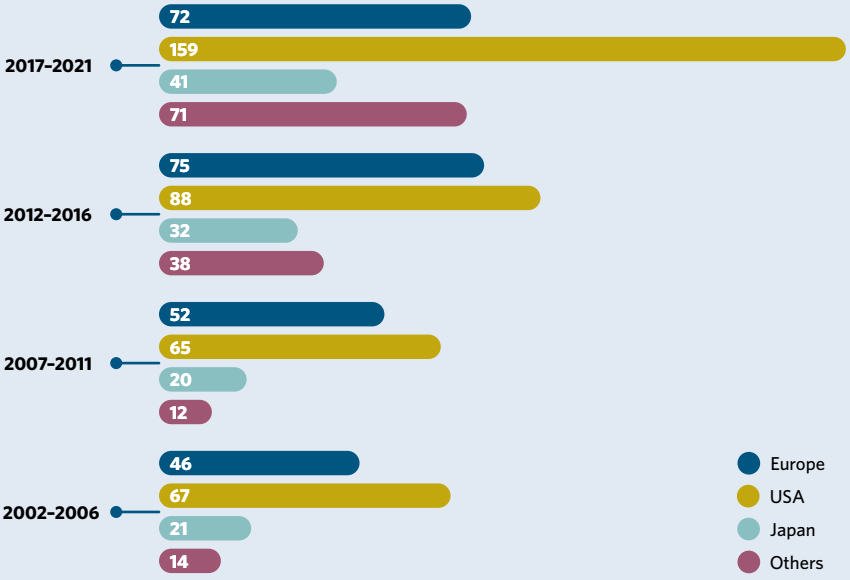
* Financial and banking, electricity, paper industry, recreational goods, and many more | numbers in %

Source: The 2022 EU Industrial R&D Investment Scoreboard

In the area of research & development, the "health care industry" (pharmaceutical, biotech and medical device industry) ranks second behind the information and communications technology industry: € 235.3 billion were invested in research & development in 2021; this corresponds to approx. 21.5 % of sales.

4.5 Medicinal product innovations

New molecular entities by region



Data in absolute values

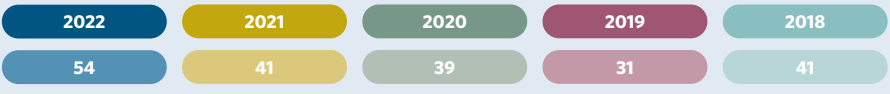
Source: SCRIP, EFPIA

- In **2022, 89 new medicines for human use** were approved in Europe (EMA).
- **41 of these contain a new active substance.**
- New approvals are for the treatment of cancer, infectious diseases, diseases of the central nervous system, cardiovascular system, inflammatory diseases, etc.
- In 2023, new products are also expected to be launched for the treatment of cancer (almost one third of the new drugs), for the treatment of infectious diseases, and for the treatment of congenital genetic defects, among many more.

Source: EMA, vfa, IQVIA, EFPIA

In the last five years, **a total of 203 drugs** with a new active substance have been approved in Austria. On average, 41 new treatment options are available each year.

Number of innovations in Austira



Data in aboslute values

Source: AGES 04/2023

Timeline of pharmaceutical developments

Important milestones in drug development since the 1850's are listed here: Timeline of pharmaceutical developments:

Year	Milestone
2020	First vaccines against COVID-19, with a development time of less than a year, the all-time fastest developed vaccines ever
2020	First drug against the viral disease hepatitis D
2020	Causally effective drug against cystic fibrosis, potentially applicable to around 60 % of patients (instead of just a small percentage)
2020/21	First selectively immunosuppressive drugs against atopic dermatitis (= neurodermatitis)
2021	First antiviral antibodies against COVID-19; with less than two years development time, the fastest developed therapeutic drugs with new agents since the introduction of drug approval.
2022	First drug against severely accelerated aging caused by Hutchinson-Gilford-Progeria Syndrome or progeroid laminopathy
2022	First gene therapy for people with haemophilia A
2022	First drug against certain genetic forms of obesity
2022	First oral and variant-independent antiviral against SARS-CoV-2

Source: VFA, excerpt – timeline of pharmaceutical developments (All the information provided refers to the year in which the medicinal product was first marketed internationally.)

4.6 Intellectual property rights

The value of a medicinal product is based not only on its therapeutic achievement but also on its research and development achievement. This is subject to special protection as intellectual property. The term "intellectual property" (IP for short) includes copyright and related trademark rights, trade secrets and industrial property rights (patents and utility models, brands and designs). This protection of intellectual property constitutes the foundation for any research-based company to continue to invest in research and thus bring innovative products onto the market.

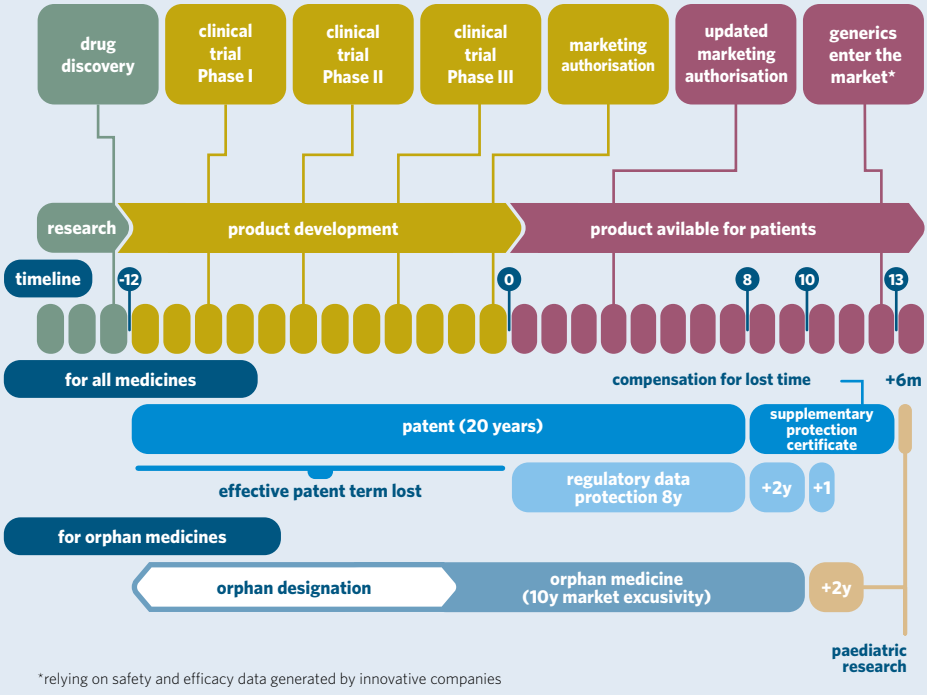
The protective effect of the intellectual property is the best incentive for investments in the area of research and development.

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 twelve years elapse. This period is necessary for pre-clinical testing and the official marketing authorisation process (see chapter 4.2 and chapter 5). Thus, on average, the actual effective life of a patent is only about eight years.

The effective useful life of a patent amounts to eight years on average.

After expiration of the patent and data protection, other companies may produce and sell medicinal products with the same active substance (generics) or with similar active substances (biosimilars) – see chapter 4.1. After expiration of the corresponding property rights, original medications can therefore no longer provide a contribution to refinancing research and development costs.

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



*relying on safety and efficacy data generated by innovative companies

Source: IQVIA, PHARMIG

The table below provides an overview of different forms of intellectual property rights and their historical purpose:

IP Protection Tool: Patent

Purpose:
Encourage private companies to invest in R&D by protecting any invention from copying for a limited period, during which the patient holder can receive a return on investment.

Details:
- 20-year exclusivity term from the date of filing
- Publication of details of the invention 18 months after application
- Types of inventions: substance, process, use, improvement, formulation, device
- Patentability criteria: novelty, non-obviousness, usefulness
- Must be enforced by the patentee

IP Protection Tool: Restoration (PTR) or Supplementary Protection Certificate (SPC)

Purpose:
Extend exclusivity for a pharmaceutical product that is protected by a patent to compensate for part of the time lost during the lengthy development period (induding clinical trials) before a generic or biosimilar version can be made available on the market.

Details:
- Maximum duration of 5 years
- Maximum total exclusivity 15 years from marketing authorisation (MA)
- Only for products with an MA
- Only one SPC per product (i.e. active ingredient or combination of active ingredients)

IP Protection Tool: Regulatory Data Protection (RDP)

Purpose:
Protect pharmaceutical developers' investment in generating the pre-clinical and clinical data required to obtain a marketing authorisation from unfair commercial use.

Details:
- 8+2 (+1) years
- 8-year data exclusivity: generic manufacture cannot rely on the data for MA purposes
- 2-year market protection: no generic can be placed on the market
- I-year additional protection if a new indication is discovered within the first 8 years

IP Protection Tool: Orphan incentives

Purpose:
To ensure that patients suffering from rare conditions have the same quality of treatment as any other patient in the EU, and to stimulate the development of treatments for rare diseases.

Details:
- 10 years of market exclusivity
- Protocol assistance, reduced fees for regulatory activities, additional incentives for SME's
- New, additional indication or extension of the existing orphan indication, requires a separate assessment by the EMA and marketing authorisation decision by the European Commission.

IP Protection Tool: Paediatric incentives

Purpose:
To facilitate the development and availability of high-quality medicines suitable for children and to support the industry by helping to offset the additional costs of conducting paediatric research.

Details:
- 6-month extension to the supplementary protection certificate (SPC). which protects the product
- If the medicine is designated as an orphan medicinal product, the 10 years of market exclusivity provided by the Orphan Regulation can be extended by a further 2 years.

Source: www.iqvia.com

4.7 Usage of health data

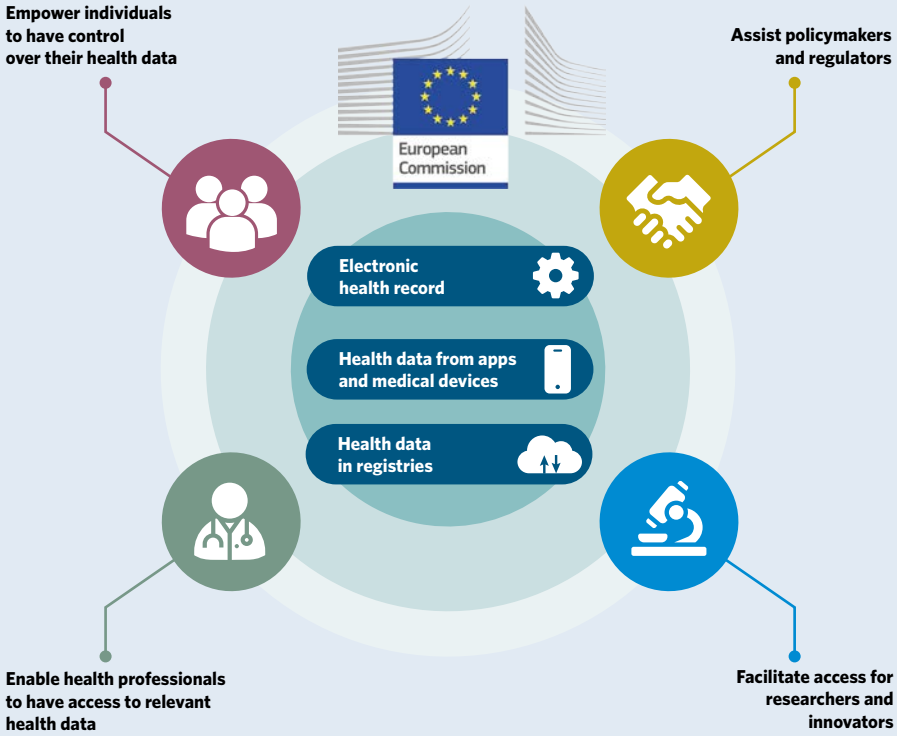
The amendment to the Federal Act amending the Federal Statistics Act (BStatG) 2000 and the Research Organization Act (FOG) (400/BNR), was passed in November 2021. It represents a significant milestone in improving scientific access to public, deidentified statistical and registry data while respecting data confidentiality provisions. For the purpose of scientific research, access to microdata from Statistics Austria as well as to data from registries (access standardised by FOG) was granted to authorised research institutions. Statistics Austria was commissioned to set up a technical platform, the **"Austrian Micro Data Center"** (AMDC). Since July 2022, researchers have been able to access anonymised data remotely via the AMDC. On the website of the AMDC at www.statistik.at, further information is publicly available, such as the micro data catalogue, which contains the available register data, authorised research institutions, technical and legal requirements in connection with applications, ongoing projects, and much more.

At the European level, the implementation of the **"European Health Data Space"** (EHDS) – one of the priorities of the European Commission – is scheduled. The central element is the orientation towards the common good: structured collection, connection and careful use of health data enables evidence-based decisions for optimised planning, quality care and future-oriented research. In addition to citizens of the European Union, regulatory authorities and policymakers will benefit from secure and transparently accessible data.

Individuals – EU citizens – will benefit from **primary data use**, such as cross-border exchange also of health data, i.e. information on diagnosis, treatment, care and reimbursement of insurance benefits. **Secondary data use** is the anonymised reuse of existing information for the purpose of scientific research (for further development of therapies and medicines). Patients subsequently benefit from this. It goes without saying that data protection has top priority in any form of data use. European regulations, directives and laws provide the legal basis*.

At the beginning of May 2022, the European Commission presented a draft regulation on the EHDS. The proposal is now being negotiated with EU legislative bodies (European Parliament and Council). Implementation is planned for the year 2025. Further information: Europäischer Raum für Gesundheitsdaten (EHDS) (europa.eu)

* Data Protection Regulation (GDPR), Data Governance Act, Data Act and Directive "on measures to ensure a high common level of security of network and information systems in the Union" (NIS Directive).



Source : European Commission

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16,684

approved medicinal products for human use in Austria (315 of which are available over the counter)

83

central EU approvals for medicinal products in 2022

5. Marketing authorisation for medicinal products

Medicinal products may only be placed on the market by the marketing authorisation holder (MAH) after they have been officially approved or registered by the authorities. The authorisation is granted if the applicant can demonstrate that the expected benefits of a medicine exceed the expected side effects. The proof is provided by submitting pharmaceutical, preclinical as well as clinical data.

5.1 Procedures

There are different procedures to obtain a marketing authorisation:

- **National procedure**
  The (purely) national authorisation procedure 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 awards the marketing authorisation. Legal basis: National medicinal product law of the EU member states

- **Mutual recognition (MRP)/decentralised procedure (DCP)**
  This authorisation procedure is applicable when the medication is to be approved in more than one EU member state. This procedure is based on the principle of mutual recognition of marketing authorisations by the other 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 this country. 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 authorities of the EU members involved in the process. Every member state shall issue a national marketing authorisation once the procedure has been completed. Legal basis: Policy: 2001/83/EG

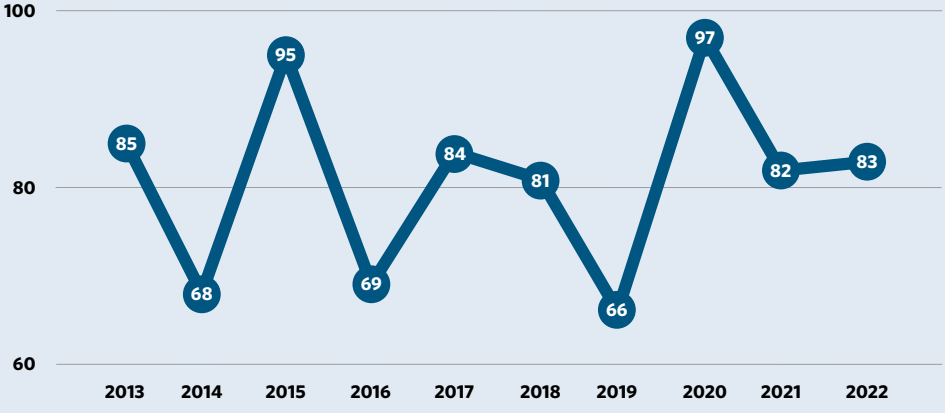
- **Centralised procedure (EU)**
  A centralised procedure has been in place since 1995, at the completion of which a European authorisation is awarded. In a centralised procedure, the authorisation is granted by the European Commission and is valid in all EU member states. Legal basis: Regulation (EG) No. 726/2004

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 Amsterdam. Based on the EMA evaluation, the European Commission awards an EU authorisation for all member states.

Centralised procedures for medicinal products in the EU



Source: European Commission (per April/2023)

5.2 Authorised and registered human medicinal specialities in Austria

If a pharmaceutical is approved according to the MPA, it is designated as a proprietary medicinal product. Competent authorities in Austria are BASG (Federal Office for Safety in Health Care), AGES MEA (Agency for Health and Food Safety Medical Market Surveillance) – see organisation chart: www.basg.gv.at

The legal basis is the Health and Food Safety Act (GESG).

Approved medicinal products for human use in 2022	9,157
Chemical medicinal products	7,971
Homeopathic medicinal products	543
Biological medicinal products	383
Herbal medicinal products	164
Radioactive pharmaceuticals	45
Medicinal gases	37
Medicinal products that represent a monography of the ÖAB/Ph.Eur*	14

Source: Austrian Medicines and Medical Devices Agency

Registered medicinal products for human use in 2022	3,996
Homeopathic medicinal products	3,005
Pharmacy-proprietary medicinal products	660
Traditional use registration for herbal medicinal products application	210
Allergen manufacturing procedure	121

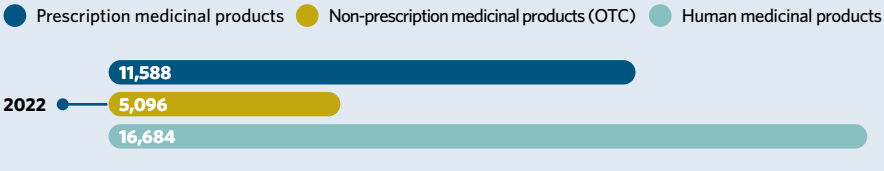
Source: Austrian Medicines and Medical Devices Agency

* § 9c Medicinal Products Act

5.3 Prescription status

(human medicinal products incl. homeopathic medicinal products)

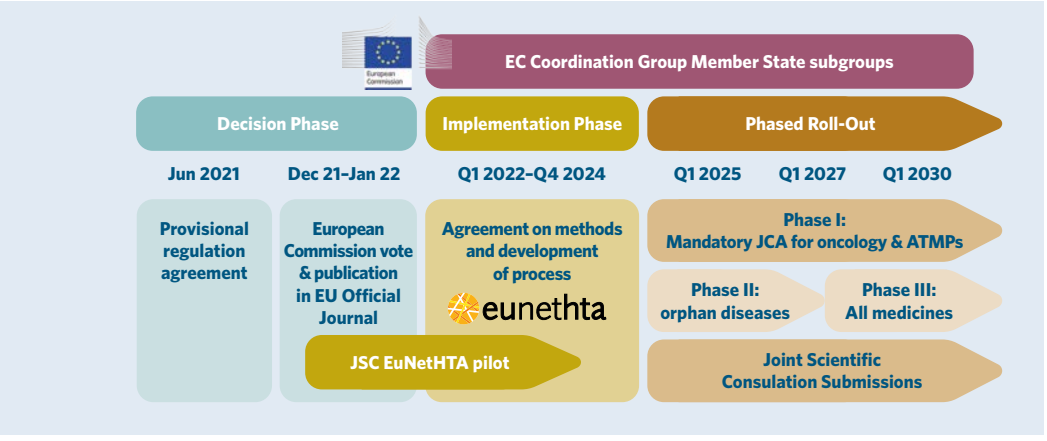
The prescription status of the medicinal products is determined during the authorisation procedure. The Prescription Act together with the Austrian Prescription Ordinance (Rezeptpflichtverordnung) are the legal basis for this decision. **Around 31 % of the medicinal products for human use approved in Austria are available as non-prescription medicinal products in pharmacies.**



Source: Austrian Medicines and Medical devices Agency

5.4 Health Technology Assessment (HTA)

Health technology assessment (HTA) is the **systematic evaluation of medicinal procedures and technologies** (a large proportion of which relate to drugs and medical devices) in health care. For this purpose, all available data are presented and evaluated under a specific question. HTA reports are often the basis for decisions by physicians, health authorities, health insurers and other payers on the medical and economic value, as well as the social and ethical framework of the respective issue. Following a legislative proposal from 2018, the European Commission issued the "Regulation on Health Technology Assessment" (Regulation (EU) 2021/2282) on January 12, 2022. It will apply from January 2025. It regulates how health technology assessments are to be carried out at European level in the future. How the findings of the joint clinical evaluations are handled remains a matter for the individual EU member states. The implementation and rollout phase is set until 2030. www.sozialministerium.at



Source: European Commission, EFPIA

The regulation aims to

- efficiently use **resources** and improve the **quality of HTA throughout** the EU,
- **avoid duplication** of work between national **HTA-bodies and industries**,
- prove **certainty to companies** and
- provide long-term **sustainability** of **HTA cooperation in the EU**
- and thus, to give **patients** better and faster access to **innovative medicines and medical devices** in the EU.

The administration of health services, including pricing and reimbursement for pharmaceuticals, remains the responsibility of member states. ec.europa.eu

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Pharmacovigilance

contributes to the protection of patients
and public health

AMVO

is responsible for the governance of the medicinal
product verification system in Austria

6. 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, through providing timely information about the safety of medicinal products to patients, health care 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.

6.1. 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 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 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 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. 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.

Reporting of side effects and evaluation

After marketing authorisation manufacturers and drug authorities systematically search for additional, still unknown side effects. The most important source of information for this is spontaneous reporting: in this process, health care professionals such as physicians and pharmacists report suspected cases of side effects that have occurred in patients under their care. Since 2012 patients themselves have also been able to voluntarily report side effects. For them, there is an online adverse reaction reporting form on the BASG website www.nebenwirkung.basg.gv.at. Physicians, pharmacists and other health care professionals are required by law to report side effects.

The BASG records all suspected adverse reactions to medicines and vaccines that have occurred in Austria. After processing and assessment, the data are forwarded to the EMA in accordance with the applicable European regulations. This makes the data available to all national drug authorities for ongoing safety monitoring.

The risk-benefit balance of medicinal products is continuously monitored in close cooperation between the EU authorities. The Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA analyses all aspects relevant to the safety and efficacy of a drug. If necessary, new side effects are included in the specialisation and usage information or other measures are taken in order to ensure safe and effective use.

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.

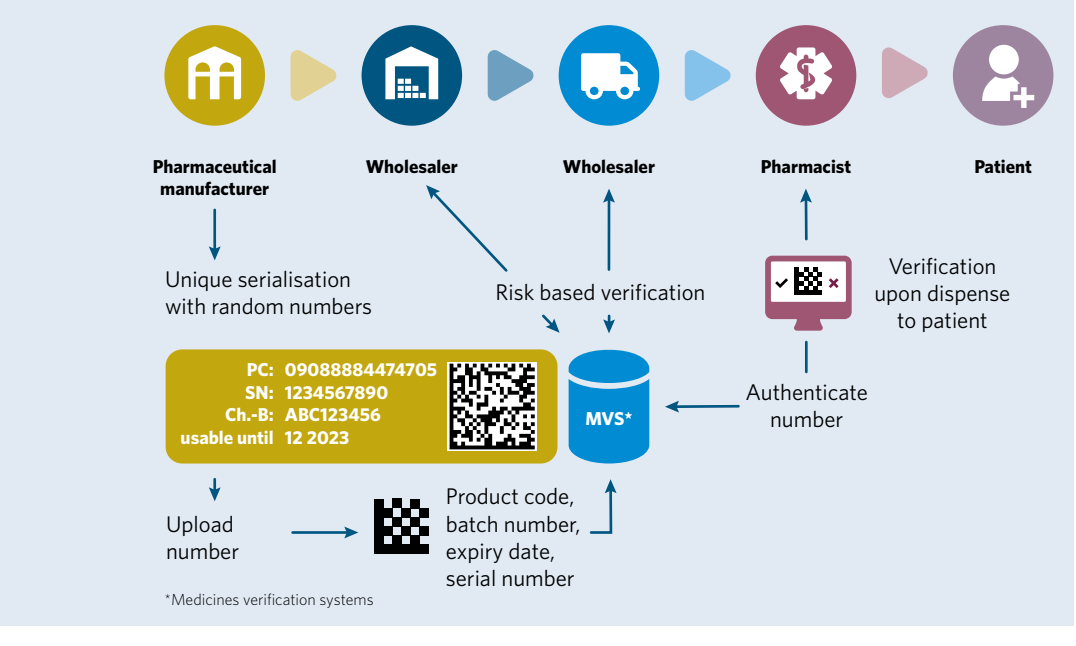
Amendments to the European pharmacovigilance laws in 2012 brought an increasing shift in administrative tasks in the area of drug monitoring from the member states to the European Medicines Agency (EMA). This was accompanied by a large increase in fees. As well as an annual fee for the maintenance of the EMA IT systems, additional five- to six-figure procedure-based fees are charged for PSURs, post-authorisation safety studies and pharmacovigilance-related referrals. 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). It is estimated that an average pharmaceutical company with a wide range of active ingredients could pay up to € 20 million annually in pharmacovigilance fees alone.*

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

6.2. 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 2016/161 on "detailed rules for the safety features appearing on the packaging of medicinal products for human use". This regulation has been effective since February 9th, 2019.

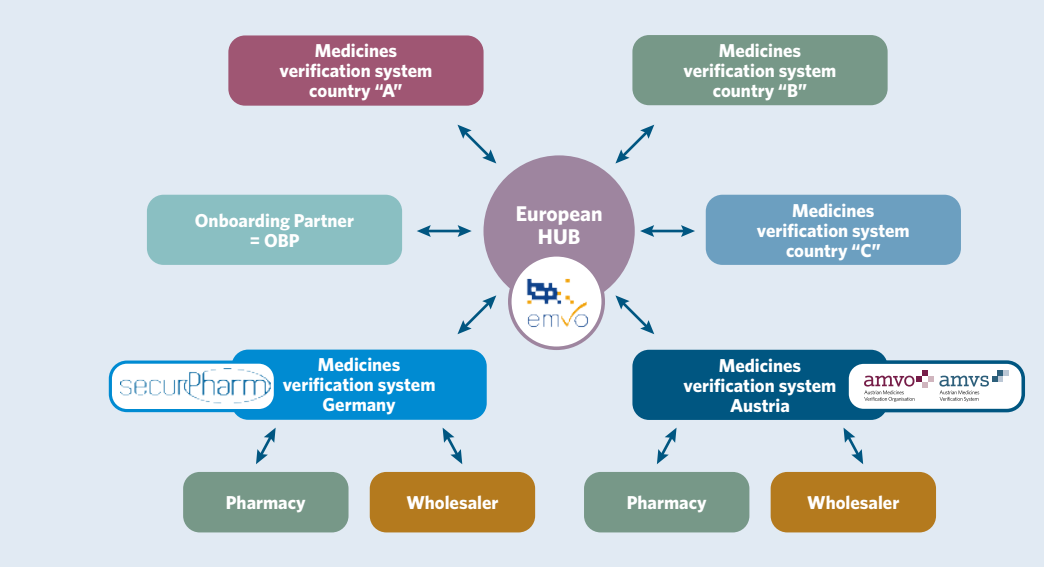


Source : EFPIA

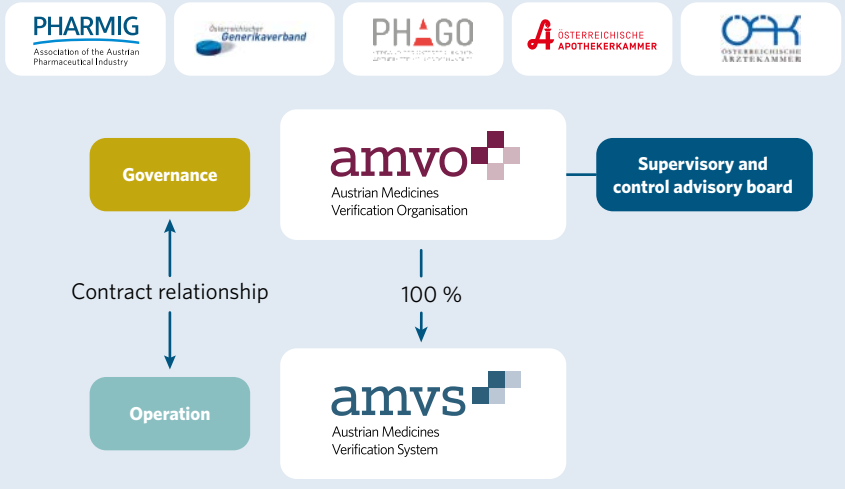
In principle this affects all prescription drugs for human use, exceptions can be found in Annex 1 and Annex 2 of the delegated regulation. All medicinal products must be equipped with a unique, randomised serial number, which will be encrypted in a two-dimensional barcode (data matrix), together with the batch number and expiry date. This is 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). A deactivated serial number means that the package has already been issued. If the same serial number reappears at a later time, it indicates a suspicion of falsification.

The European system of serialising medicinal products

For this process, in accordance with the Delegated Regulation, a data storage and retrieval system was set up by the pharmaceutical manufacturers and marketing 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. The EU hub is operated by EMVO (European Medicines Verification Organisation).



Source: EFPIA



Source: PHARMIG

Implementation in Austria

PHARMIG, the Austrian Generics Medicines Association, PHAGO (Austrian Association of Full-Line Pharmaceutical Wholesalers) and the Austrian Chamber of Pharmacists together founded the AMVO (Austrian Medicines Verification Organisation) in Austria. AMVO was officially registered in the Austrian association register in December 2016 and is responsible for the governance of the medicinal product verification system. In August 2017 the Austrian Medical Chamber joined AMVO. At the same time, the members of the AMVO committed themselves to work together to clear up and handle any cases of suspected fraud. The competent authorities are integrated through the supervisory and control advisory board and can therefore fulfil 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 has to guarantee the perfect functioning of the national system. All affected stakeholders are connected to the system operated by AMVS GmbH in order to fulfil their legal obligations. The AMVO is responsible for the governance of the medicinal product verification system.

For further information, please visit:
www.amvs-medicines.at or www.amvo-medicines.at

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1.4 years

Life expectancy significantly increased
between 2007 and 2011

approx. 400,000

people in Austria suffer from
rare diseases

4,198 applications

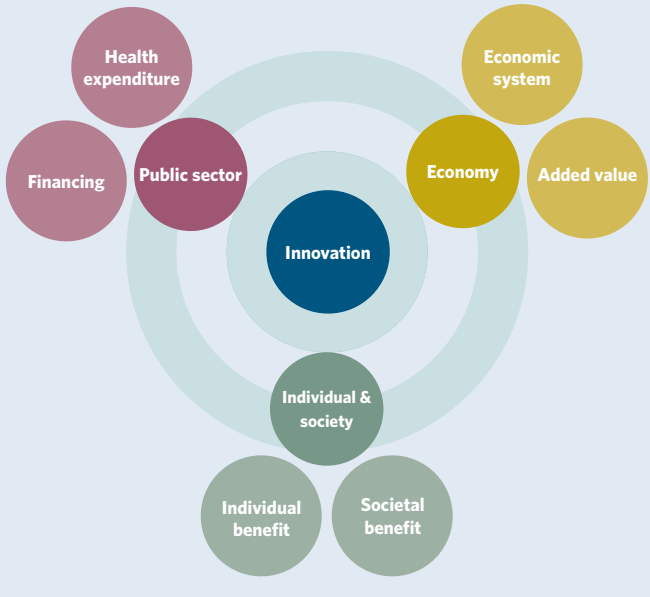
between 2000 and 2022 with
231 approved orphan drugs (ODs)

7. Benefits of innovative therapies

Medicinal products make an important contribution to our society: they help heal, relieve or protect against diseases. Based on new scientific findings – about fundamental biological processes or specific diseases – novel drugs are developed with which patients can be treated (even) better or for the first time. Pharmaceuticals and medical progress make a significant contribution to longer life expectancy. A study conducted in Germany shows the link between pharmaceutical innovation and life expectancy: in the period from 2007 to 2011, life expectancy increased by 1.4 years, with one-third of this improvement attributed to newer drugs (Liechtenberg 2012). The effects of medical innovations extend far beyond direct benefits to patients. They can reduce health care spending, for example by shortening or avoiding hospital stays, as well as the amount of care needed by family members. Sick leave can also be reduced or even avoided and the health care system as a whole can be improved at the process level as a recent study by the IHS shows.

Where and how innovative drug therapies have an impact – on the individual and society, on the public sector and the economy – is shown by an IHS study conducted in 2021. In addition to drugs, innovations in health care also include diagnostic or therapeutic procedures whose effects extend beyond the **direct benefits for patients (longer life expectancy and improved quality of life)**. Social effects can be seen, for example, in shorter or avoided hospital stays and reduced care requirements for relatives. Innovations are relevant in various areas of health care; in prevention, they

Conceptual representation
Impact of innovation in health care



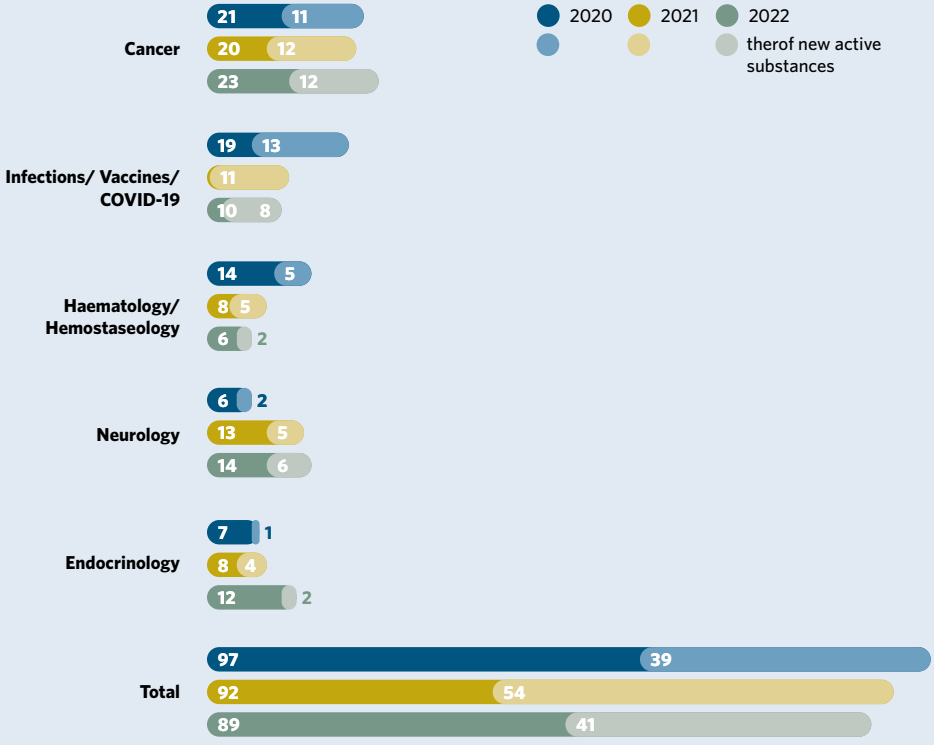
Innovative therapies impact individual/society, economy and public sector

Source: Value of Innovation in Healthcare, IHS 2021

benefit society as a whole, because cases of illness can be avoided. The burden of disease is reduced both for those affected and for society if there is no disease at all. An example is the global COVID-19 pandemic: Prevention and the development of a vaccine. For the public sector, this means lower expenditures for health (rapidly restores working capacity, healthy workforce). The economic system benefits from innovations in the health sectors by creating jobs and purchasing power.

The following examples illustrate how innovations in drug development can change the entire health care system and the opportunities they offer – first and foremost to save lives and giving people suffering from diseases a better quality of life again.
Between the years **2020 and 2022, 278 medicinal products were recommended for approval by the EMA, 134 of them with a new active ingredient.** Most innovations were in the area of cancer, neurology and infectious diseases.

Innovations per therapeutic area



Data in absolute values

Source: EMA Medicines for Approval 2020-2022

7.1 Cancer

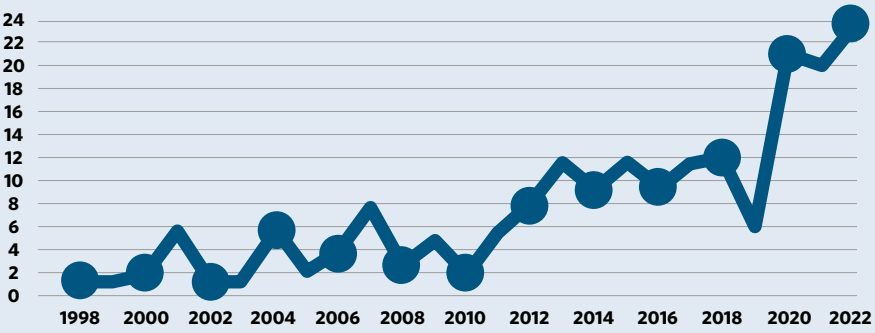
- By the **end of 2020, 384,883 people in Austria** were living with cancer (of whom 53 % were women and 48 % men). That equals **4 % of the total population**.
- This represents a **significant increase compared to 2007** (approx. 270,000 people with cancer) and can be attributed to the following factors all working in conjunction with each other: **demographic aging**, a general **rise in life expectancy** and the **improved survival chances** of afflicted persons.
- By the **end of 2020, 43,014** new **cancer diagnoses** had been documented.
- The most common **malignant tumours** in women relate to the **breast**, in men to the **prostate**, followed by **lung** and **colon** or **rectum** (both sexes).

The risks of a new diagnosis and the risk of mortality both decreased significantly. At the same time, the survival rate for people with cancer increased. Austria ranks 5th in the international comparison with a relative 5-year survival of 61% between 2013 and 2017 (Euroare, Statistics Austria 2023). This is due to improved diagnostics (screening programmes, earlier diagnosis), medical advances, and new treatment methods.

In the past 10 years modern cancer treatments 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. With new diagnostic and therapeutic possibilities, the treatment of cancer also becomes easier and easier (see chapter 3.4). Furthermore, affected individuals can actively take part in working life for longer. The mortality-related loss of productivity has decreased in Austria from 2018 vs. 1995 by approximately 21 % – Europe wide by 15 %. Cancer research and treatment is very different and complex. Today, it is assumed that there are more than 250 types of cancer. Factors like form, structure, genetic modifications and molecular properties influence the growth of the tumour. In addition to common forms of treatment – surgery, radiotherapy, and chemotherapy – patients have access to biopharmaceutical therapies such as targeted and immuno-oncological therapies.

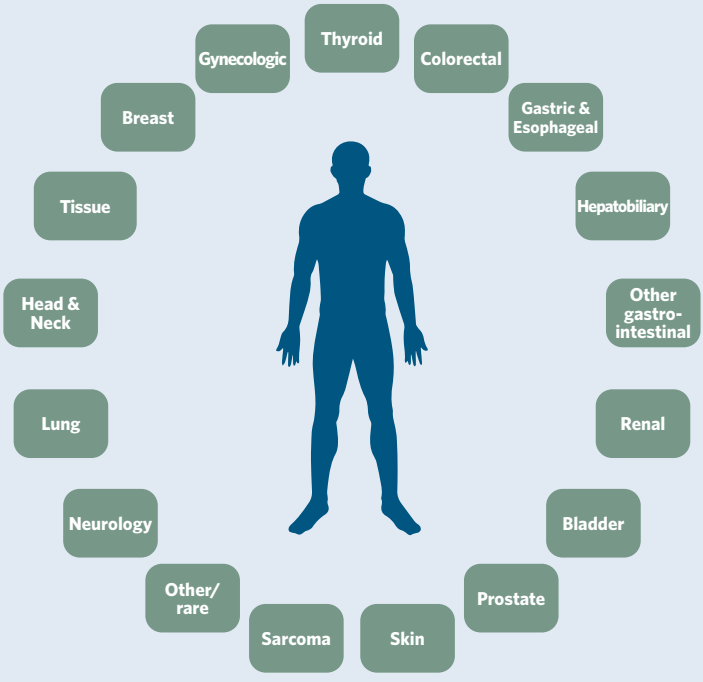
- **In the period 1995–2020, 145 new drugs were approved** in oncology.
- **In the last two years, 43 new cancer drugs** were launched in Europe – **24 of them with a new active ingredient**.
- Numerous new medicines are in development at the moment
- Also, in Austria **oncology** (approx. 50 % of all studies in Austria) is the **most researched therapeutic area** (see chapter 4.2 Clinical research).

Number of cancer drugs and indications approved by the EMA



Source: EMA

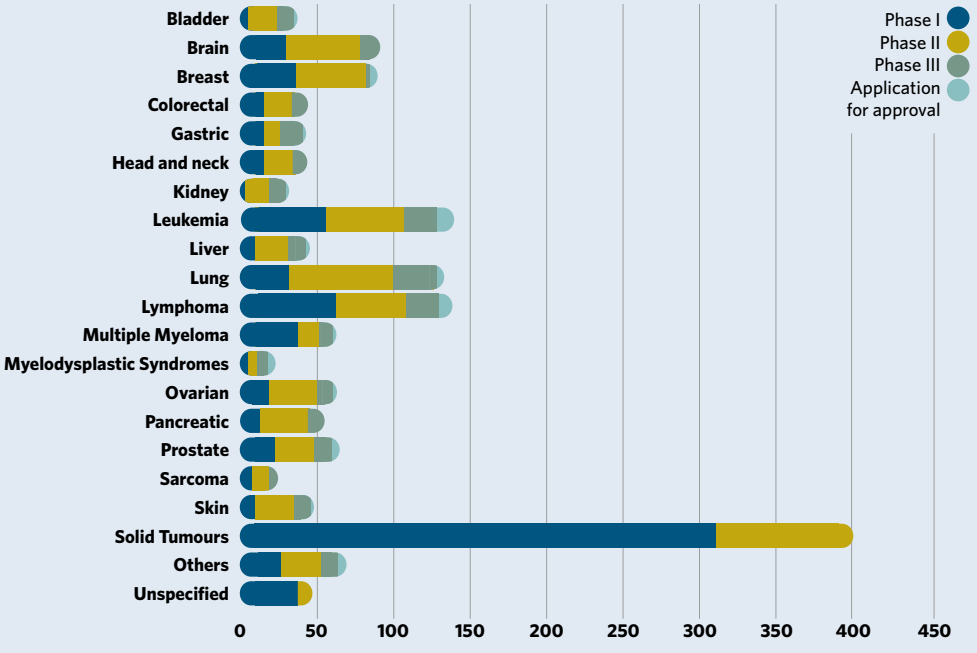
Novel active substances in oncology by indications:



Source: IQVIA

Outlook: according to IFPMA, more than 2,740 drugs are in development for the treatment of more than 20 tumour types using novel approaches, like gene analysis (e.g. CRISPR), CAR-T-therapies, viral therapy (mRNA technology), immunotherapies or antibody-drug conjugates.

Medicines and vaccines in development against cancer



Source: PhRMA 2020

The cost of cancer treatment in Austria, measured as a proportion of total health care expenditures, remains constant at around 6.4 %, despite significantly higher incidence rates and longer treatment periods (see 2014: 6.5 %). There is a clear correlation between the level of expenditure on cancer care and treatment outcomes or survival rates: The higher the investment in innovation-oriented cancer care, the better the prognosis for cancer patients.

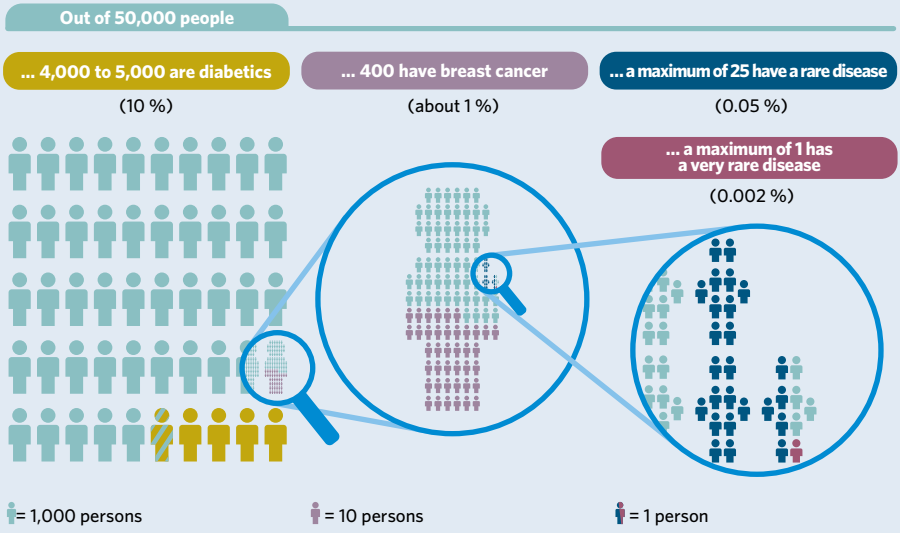
Source: IHE Comparator Report 2019, EMA 2019

7.2 Medicinal products for the treatment 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 over 50 % of these affect children. In Austria about 400,000 people (i. e. 6–8 % of the population) suffer from 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 was adapted in 2000 specifically 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 reduced marketing authorisation costs, 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 rare? A comparison:

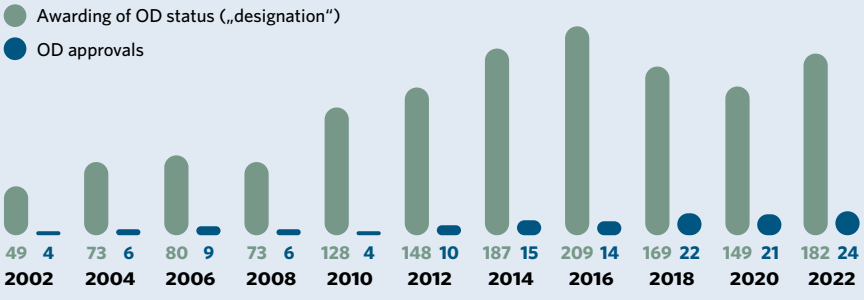


Source: European Commission

3,678 applications for orphan drug status were filed from 2000 to 2022. In 2,734 cases orphan drug status was awarded but, so far, only in 231 of these cases marketing authorisation has been granted. The great number of applications (4,198) reflects the high level of research work done in this area and it shows that the incentives offered by the regulation are recognised by the companies. However, the low success rate (231 approvals) demonstrates the high entrepreneurial risks for companies.

In **2022, 24 orphan drugs** could be approved again. These include new medicines for rare diseases in the fields of haematology, cancer and metabolic diseases, which have the potential to significantly help patients and for which there are currently no other approved products.

Awarding of orphan drug status vs. approval of orphan drugs (2000-2022)



Data in absolute values

Source : EMA Orphan Medicinal Product Designation, Overview 2000-2022

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 Federal Ministry of Health and written by the NKSE (National Coordination Office for Rare Diseases). The starting point for the plan was drawn up 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 health care objective, the health care reform or the children and youth health care strategy.

The NAP.se combines plan and strategy and defines 9 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 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 medicinal 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, as well as the evaluation of the reports, and information on the NKSE can be found here: www.sozialministerium.at

The NAP.se evaluation report provides, among other things, more clarity regarding further implementation and recommends ongoing monitoring of the implementation of measures.

7.3 Plasma donation in Austria/ products made from blood plasma

The medicinal products derived from human blood plasma (more than 60 authorised medicinal products) have numerous applications, such as

- the **treatment** of **congenital** and **acquired immune defects**,
- **haematology** incl. **haemophilia**,
- for **serious injuries** and **burns** (for haemostasis and for wound closure),
- for **liver diseases**,
- for **severe infections** (such as **COVID-19; plasma-based therapy** was injected for treatment),
- for **neurological diseases** and
- in **oncological pathologies**.

The cooperation of local research and development facilities with hospitals, universities and local industrial manufacturers forms the basis for the development and the worldwide launch of new products.

Blood plasma has been donated and processed in Austria for about 55 years, the longest tradition in Europe.

Plasma donation and processing in Austria:

- **24 plasma centres**
- about **40.000 donations** and about 510,000 litres of plasma in 2018
- **58 litres of plasma** per **1,000 inhabitants: Austria** is part of the **world's top plasma collection countries** and leading in **Europe**
- **€ 1.5 to € 5 million** each year, each **plasma centre** contributes to the local economic performance
- over **400 employees** in the **Austrian plasma centres**
- **2 plasma processing companies** with a **capacity** of approx. **4 million litres of plasma per year** (about **15 %** of the **worldwide capacity**)
- **extraction** of **plasma components**, fully integrated **production** of high-quality **pharmaceuticals** and **export** to over **100 countries**
- more than **5,000 jobs**

7.4 Vaccination

The widespread use of vaccinations saves 2 to 3 million lives every year (excl. COVID-19). An increased worldwide vaccination rate could prevent further 1.5 million deaths. Vaccinations have multiple uses:

- they **protect the vaccinated** from **illnesses** – just under **30 illnesses** can be **prevented** by **vaccination** today.
- they **reduce** the **long-term effects** or **disability** resulting from it.
- they help the **health care system** to **save money** by, among other things, reducing **hospital stays** and **costs** for **doctor consultations**.

For some illnesses which can be prevented through vaccination, everyone getting a vaccination contributes to protecting the community. If enough people are vaccinated, so-called "herd immunity" is achieved. Then everyone who was unable to get vaccinated (such as vulnerable infants or elderly people) will also be protected. The number of people at which this "herd immunity" is reached differs from illness to illness.

In the long term, at least, epidemics can be reduced, and entire illnesses – such as smallpox or polio – can be repressed or exterminated by vaccination programmes.

Calculations by the Institute of Pharmaeconomic Research (IPF) from 2019 and 2023 show that vaccination against influenza, pneumococcus, HPV, and from the years 2021 and 2023 against COVID-19, also pays off for society and the health system.

Vaccines – just like all medical products on the market – are monitored for their safety (see chapter 6 Pharmacovigilance).

The vaccination system in Austria

The Austrian vaccination schedule provides an overview of currently available vaccinations. It differentiates between vaccinations which are borne by public authorities within free child-vaccination programmes and those vaccinations which must be self-financed but are recommended on the basis of scientific evidence. All health insurance schemes offer a subsidy for some vaccinations, such as TBE, flu or pneumococci.

Life-Course Immunization (LCI) – Lifelong vaccination

Many immunisation programmes focus on childhood immunisations. However, scientific data shows that immunisations are important at all stages of life and for all age groups.

In Austria, the free childhood vaccination concept was introduced more than 20 years ago by the federal government, the provinces, and the social insurance funds. The goal: Give all children up to the age of 15 living in Austria access to important vaccinations. This measure has made it possible to achieve herd immunity for many infections. The free vaccination programme includes vaccinations against common diseases as well as against rarer, more severe diseases.

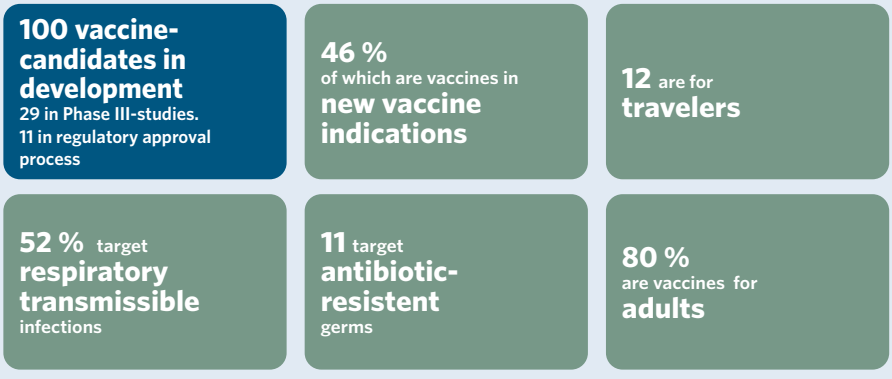
However, maintaining vaccination protection through necessary booster vaccinations is important at any age. Depending on the phase and situation of life (e. g. pregnancy, lactation, chronic diseases), additional vaccinations may be required. With increasing age, the prevalence of chronic diseases also increases, leading to a higher risk of complications and vaccine-preventable diseases with broader consequences for the quality of life and independence of those affected. The creation of an Austria-wide vaccination concept for adults with a focus on lifelong vaccination will thus become even more relevant in the coming years.

Vaccination-pipeline

Research is also taking this development into account. An evaluation by Vaccines Europe shows that the pipelines of vaccine manufacturers are well filled. There are currently 100 vaccine candidates in research and development, 81 of which are intended for adults. 27 of them are potential new COVID-19 vaccines, and there are also 10 vaccine candidates for the respiratory syncytial (RS) virus and 9 candidates that focus on seasonal influenza.

Of great importance is that 46 % of the vaccines under development are against diseases for which there is currently no vaccine for. These include, for example, vaccines against tick-borne Borrelia or Epstein-Barr virus. Eleven possible vaccines target bacteria that are already resistant to antibiotics, and 8 vaccines are being tested as therapeutic vaccines.

Over 80 % of the vaccines in manufacturers' pipelines are being tested in adults and elderly.



Source: ÖVIH, Vaccines Europe

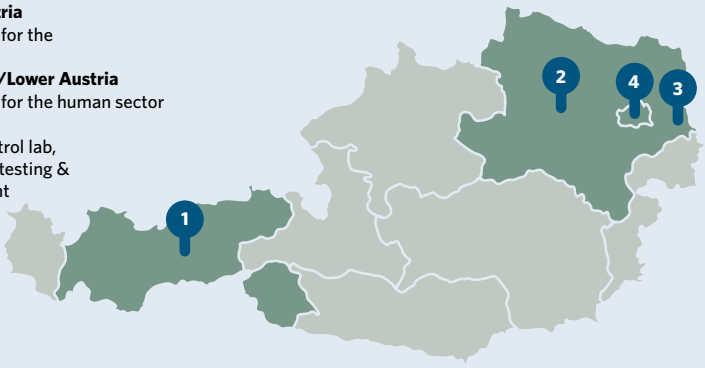
Vaccine production in Austria

Only a few pharmaceutical companies worldwide focus on the production of vaccines. Vaccines are highly complex pharmaceutical products that require long manufacturing processes and many control procedures. Austria is at the forefront when it comes to vaccine research and production.

Four out of six vaccine manufacturing companies have research and/or production sites in Austria. For example, for the human vaccine sector there is a large vaccine research centre in the Vienna Bio Center, a vaccine production facility in Orth an der Donau, a vaccine antigen production facility (= a part-production of a vaccine) in Kundl in Tyrol and a veterinary vaccine production facility in Krems.

Sites with vaccine production in Austria

1. **Kundl/Tyrol**
   antigen production for vaccines
2. **Krems/Lower Austria**
   vaccine production for the veterinary sector
3. **Orth an der Donau/Lower Austria**
   vaccine production for the human sector
4. **Vienna**
   vaccine quality control lab, production release testing & clinical development



Source: OeVIH

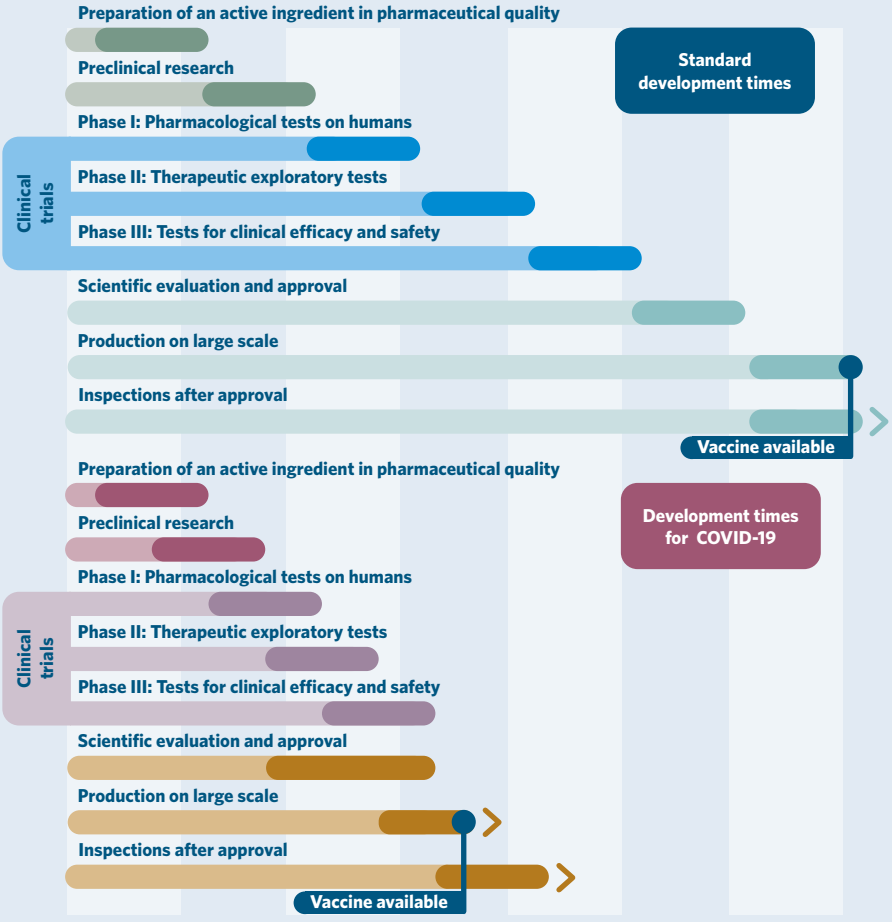
7.5 COVID-19 pandemic

With the announcement of the novel coronavirus SARS-CoV-2 on December 31st, 2019, numerous research and development projects for rapid and reliable tests to detect the virus, preventive-COVID-19 vaccines, and therapeutic drugs were launched worldwide within a very short time.

COVID-19 vaccines

It took 236 days for the first COVID-19 vaccine to become available. Contributing to this rapid development were **global collaborations between academia, organisations and companies**, rapid approvals of the study protocols and their designs, the conduct of the studies in multiple centres and countries, the high level of interest among volunteers to participate, and, last but not least, the early, cross-phase and parallel assessments (rolling review processes) by the regulatory authorities (see chapter 5.5 Regulatory characteristics).

Vaccine development in comparison



Source : www.ema.europa.eu

Overview: COVID-19 vaccines:

An **overview of vaccine research and development** is provided by the WHO: www.who.int
An **overview of the status of vaccine approval in Europe** is provided by the EMA: www.ema.europa.eu

Therapeutic drugs

Existing drugs are being tested and new ones developed for the treatment of COVID-19. The first fundamentally new drugs were approved less than two years after the project began. The fast pace is partly due to prioritisation in the companies and rapid study approval procedures in many countries.

Overview: Drugs for treatment of COVID-19

An overview of the status of vaccine approval in Europe is provided by the EMA: www.ema.europa.eu

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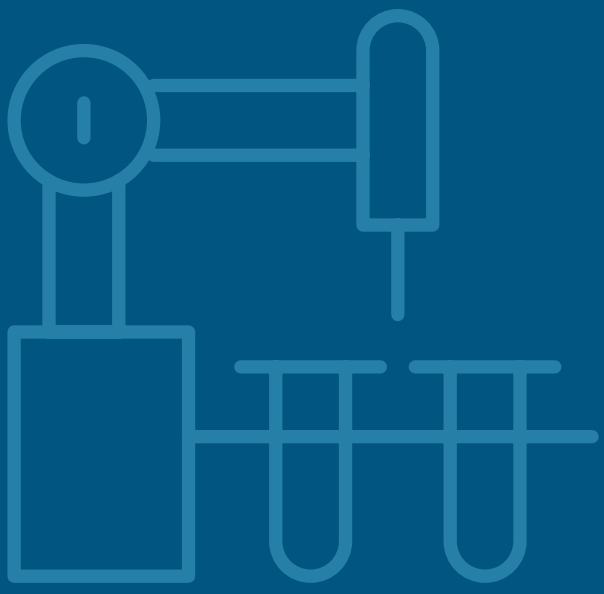
2.5 million jobs

are created by the pharmaceutical industry throughout Europe, the economic contribution is estimated at 1.4 % of the GDP

Exporting country

Austria is one of the exporting countries and has a positive trade balance



8. Pharmaceutical industry as an economic factor

Economic footprint of the pharmaceutical industry in Europe

Source: PwC 2019

The economic contribution of the pharmaceutical industry to the EU economy is estimated at € 206 billion in 2016 – of which € 100 billion are direct effects and € 106 billion are indirect effects – this corresponds to approximately 1.4 % of total economic output (GDP). The pharmaceutical industry, thus, creates approximately 2.5 million jobs across Europe (an above-average number of which are highly qualified and held by women). This corresponds to 0.9 % of the total number of jobs in the EU.

Source: PwC 2019

8.1 Pharmaceutical production in Europe

Pharmaceutical production in selected European countries

Country	Production in € million	€ per inhabitant	Estimated population 2022
Switzerland	53,195	6,061	8,776,000
Ireland	19,305	3,777	5,111,000
Belgium	20,245	1,734	11,674,000
Sweden	10,670	1,020	10,457,000
Italy	34,300	577	59,468,000
Germany	32,350	385	83,920,000
United Kingdom	25,323	373	67,886,000
Netherlands	6,180	351	17,621,000
France	23,558	346	68,039,000
Finland	1,895	340	5,577,000
Spain	16,246	339	47,890,000
Norway	1,432	263	5,435,000
Portugal	1,857	180	10,325,000
Austria	**1,434**	**158**	**9,061,000**
Poland	2,343	60	38,732,000

Source: EFPIA Statistics Austria (changes in classification compared to previous years), Eurostat 2023

In 2020, Switzerland, France, Italy, and Germany produced the majority of pharmaceuticals in Europe. Switzerland reported the highest production value per capital.

8.2 Pharmaceutical production in Austria

Pharmaceutical production in Austria, imports and exports

Values in € million

Source: Statistics Austria (changes in classification compared to previous years)

In the pharmaceutical industry, Austria is among the export countries: 2021 has a positive balance of trade (€ 550 billion).

8.3 Pharmaceutical sector in Austria

The Austrian pharmaceutical companies, which either produce medicinal products themselves („Hersteller“) or import finished medicinal products to Austria (“Depositeure “), differ greatly in the scope of their business. In addition to international corporations, the corporate landscape is dominated by small and medium-sized enterprises (SMEs). Sales range from a few € 1,000 to € 250 million per year.

*includes companies involved in the following fields: research and development, sales, supply, production

Sources: Haber, G (2016): Life Sciences und Pharma: Economic impact analysis; internal publications 2013–2020)

Every individual company makes a significant contribution to the Austrian economy and provides the best possible health care. The interactive map www.pharmastandort.at visualises the performance of the industry and shows what companies are constantly working for Austria.

8.4 Pharmaceutical industry barometer

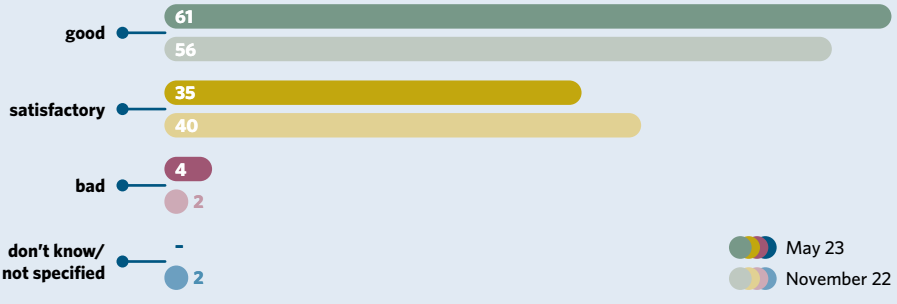
Assessment of the economic situation of pharmaceutical companies in Austria

In the fall of 2022 and spring 2023, the pharmaceutical industry barometer – a member survey by PHARMIG to assess the current and future economic situation – was conducted.

- Relatively **positive** assessments were made of the **stability of the economic environment** and the **level** of **training** of **employees**
- **Critically** seen are the involvement in **health policy, pricing** and **inflation adjustment**
- **A third of the companies** rate the current situation as **only satisfactory**
- The same number of companies expect the **situation** to get **worse** in the **next six months following** the **survey**

Current economic situation of the company

"How do you assess the current economic situation of your company?"

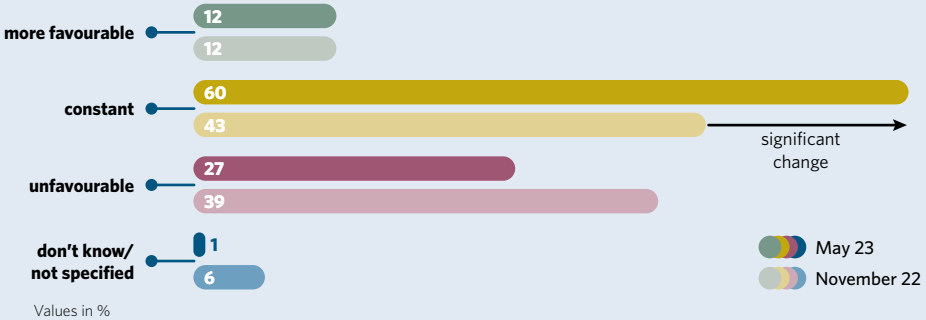


Values in %

Source: PHARMA Industry Barometer, 2022 and 2023; Peter Hajek Public Opinion Strategies GmbH

Development of the company in the next 6 months

"How do you assess the development of your company in the next 6 months?"



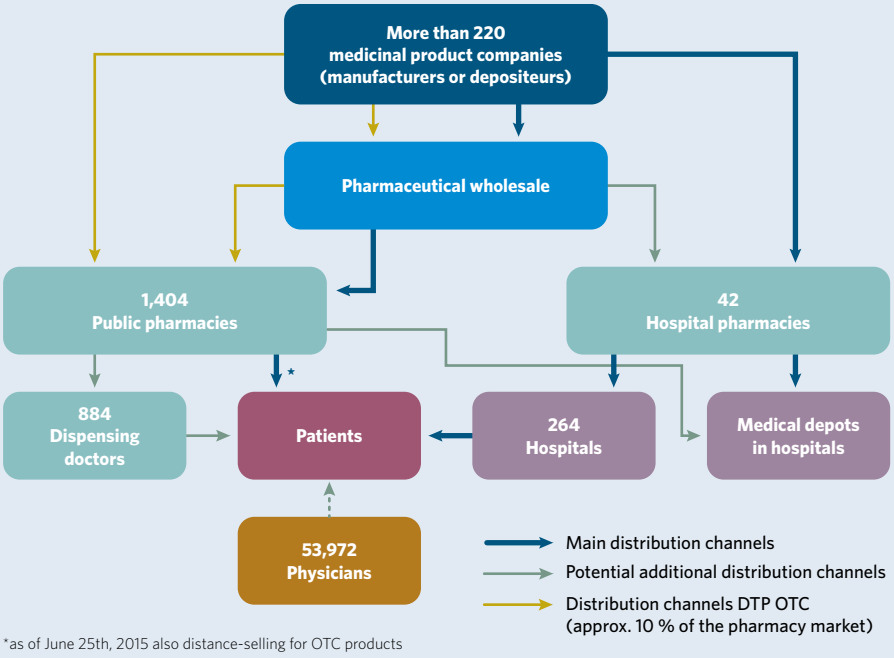
Values in %

Source: PHARMA Industry Barometer, 2022 and 2023; Peter Hajek Public Opinion Strategies GmbH

8.5 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.



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

Source: PHARMIG, Statistics Austria, IQVIA, SV, BMSGPK, Austrian Chamber of Pharmacists, 2022

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

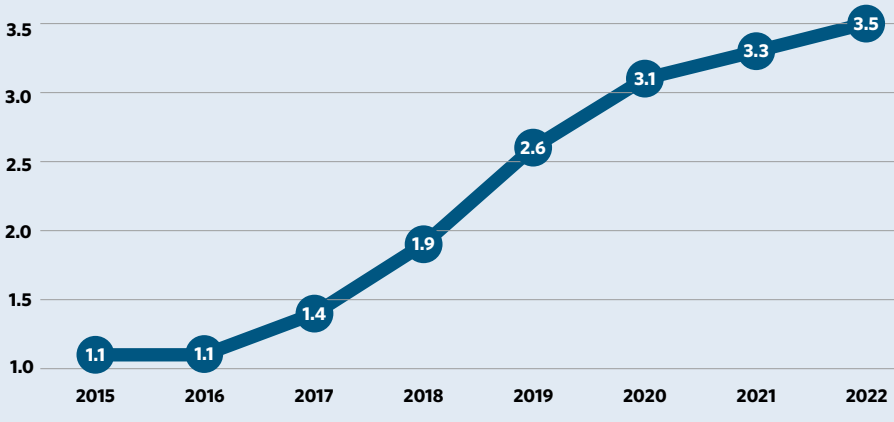
If a medicinal product is not imported or exported by the manufacturer or marketing authorisation holder, respectively, but by a third party which parallel imports/exports the medicinal product by a distribution channel which is not defined by the manufacturer or marketing authorisation holder, we call 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 for the supply. Manufacturers are not able to calculate the flows of goods, therefore shortages of supply could occur.
The law requires that labelling is adapted to the respective national standards, therefore 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 health care organisations which resort to these imports cost savings are usually very slight, because the parallel trader benefits from a major part of the price difference.

In Austria, the share of **parallel imports** has been rising continuously for several years: in 2022 it amounted to 3.46 % (vs. 1.08 % in 2015) 4.35 % in the retail market and 1.65 % in the hospital market. Products from the nervous system and oncology sectors are particularly affected.

Parallel import in Austria



Values in %

Source: IQVIA 2023

However, Austria is predominantly affected by **parallel exports** due to its low price level compared to the rest of the EU. In some cases, this leads to problems in supplying patients domestically despite the marketing authorisation holder's proven ability to deliver. For this reason, the Ordinance on Securing Supply (BGBl 20/II/30) created the possibility for the BASG to issue a temporary parallel export ban for products with sales restrictions.

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 June 25th, 2015 domestic distance selling is also possible for Austrian pharmacies. The list by the AGES MEA – Austrian Medicines and Medical Devices Agency contains information on all distance selling pharmacies registered in Austria: versandapotheken.basg.gv.at

Legal provisions are set out in the Ordinance on Distance Selling.

8.6 Drug supply

Despite all efforts in the distribution chain to ensure the supply of patients, there may be selective restrictions in drug supply availability.

According to the Regulation on Security of Supply (BGBl 20/II/30), marketing authorisation holders must report any distribution restrictions for prescription-only human pharmaceuticals since April 1st, 2020. The notifications are published in the distribution restriction register on the BASG website. Based on an evaluation scheme, BASG decides on a temporary parallel export ban for the notified products. medicineshortage.basg.gv.at

The reasons for supply bottlenecks are multifactorial and can lie within as well as outside the distribution chain:

- **long-lasting pricing pressure** and consequently a migration of manufacturing to Asia and India as well as a focus on a limited number of manufacturers
- **unexpected demand** that cannot be calculated in advance
- **shortages** of components necessary for the **manufacturing of drugs** (chemical components, intermediates, solvents, primary and secondary packaging materials)
- **quality problems in manufacturing** (contamination in the production process, defects in packaging)
- **challenges in logistics** and **storage**
- generally **longer delivery times for components** needed in production (solvents and coatings, paper for packaging and patient information leaflets, closures, plastic and glass containers)
- long-lasting **skilled worker shortage** and **staff shortage** in manufacturing and logistics
- incalculable **outflows of goods abroad** due to parallel trade (see chapter 8.5)

Measures to reduce and avoid delivery delays are being implemented and discussed at Austrian and European system and company level and are aimed at the following areas:

- **Increase in production capacity** on pharmaceutical companies' part
- Creation of national and European storage possibilities for certain, particularly supply-relevant medicines or increase in inventory
- **Improved integration of the sales restriction registers** in doctors' office software
- **Regulatory flexibility** regarding the import of medicines with package information leaflets in multiple languages or in regards to an adaptation of §4 (6) of the Prescription Drug Act with dispensing regulations for prescription drugs in emergencies
- **Implementation of a harmonised EU prevention and remedy system** to avoid duplication and to fully exploit the potential of existing data, such as those from the EMVS (European Medicines Verification System), the SPOR (Substances, Products, Organisations and Referential master data) and the EMA IRIS Platform
- **Increase in supply chain transparency** by leveraging and linking existing data, for example from national organisations set up simultaneously with the Forged Medicines Directive (in Austria it is the AMVS), from the EMVS, the SPOR, IRIS and other sources
- **Strengthening of drug manufacturing** in Europe and Austria, whereby it must be noted that a self-sufficient manufacturing of drugs would be difficult to realise due to the global supply chain. From a company's point of view (various industries including the pharmaceutical industry), the main obstacles are:
  - » High operating costs in Europe due to high staff costs
  - » Lack of local suppliers (e.g. for important materials)
  - » High dependency on imports, especially for active pharmaceutical ingredients with high volume and low complexity

Fischer, S., Knoll, V., Alleweldt, F., Vogler, S., 2023, Potential measures to facilitate the productions of active pharmaceutical ingredients (APIs), publication for the Committee on the Environment, Public Health and Food Safety, Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, Luxembourg

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Prices for pharmaceuticals on the Austrian market have been on a downward trend for years: a packaging that cost € 10 in 1996, costs in 2022

€ 6.17

The consumer price index (CPI) develops in a contrary manner: the inflation rate is

+8.6 % in 2022

9. The pharmaceutical market

9.1 Pricing for medicinal products

Pricing for medicinal products is regulated by law in Austria. The 1992 Price Act (for all human medicines) and the ASVG (for inclusion in the Code of Reimbursement) form the relevant basis for this. The Pricing Committee of the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) is responsible for the prices of medicinal products. The manufacturer's price or depot selling price (MP/DSP) forms the price basis of a medicine. The respective mark-ups (wholesaler & pharmacy mark-up – legally regulated by staggered maximum mark-ups) and value added tax are added to this price. The MP/DSP can be freely defined by the authorised pharmaceutical company, whereby the BMSGPK is informed about this price.

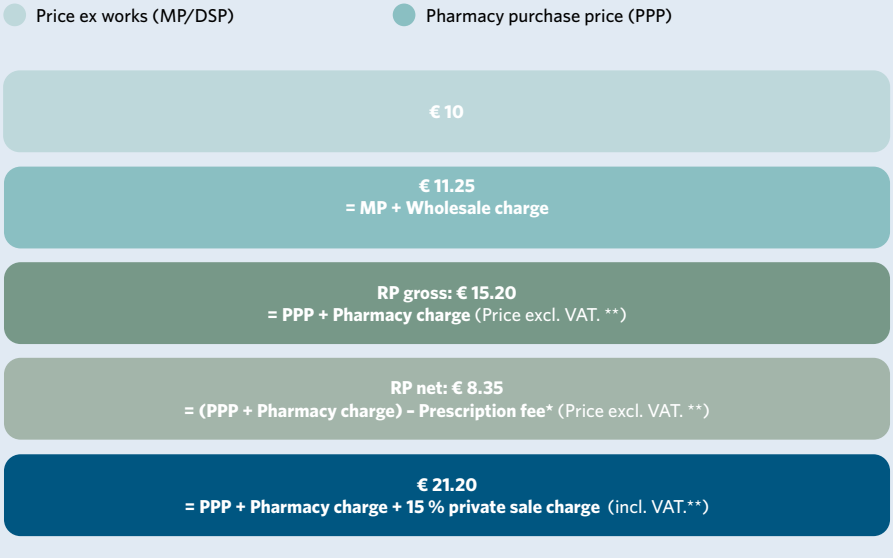
Price of medicines

- **Price ex works (MP/DSP):** 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

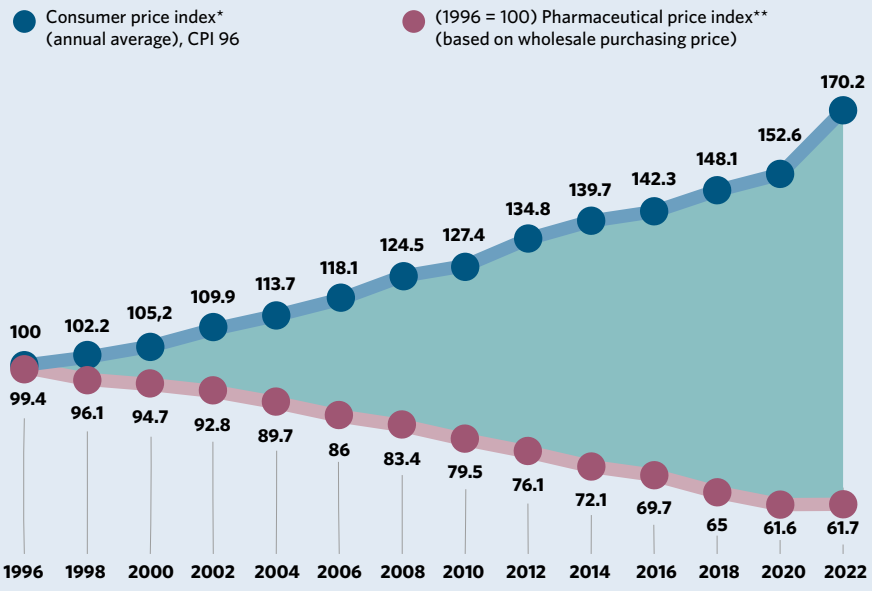
Prices of medicines example



* Prescription fee as of 01.01.2022: € 6.65; ** VAT as of 01.01.2009: 10 %

Source: PHARMIG

Price trends (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 IQVIA calculations and is an element of growth. The pharmaceutical price index incorporates changes in pricing (in %) of products which have already been placed on the market in comparison with the previous period. (see Chapter 9.2 Elements of growth)

Source: Statistics Austria, IQVIA

Prices for medicinal products already on the Austrian market have decreased annually since 1996. A fictional pack of medicine costing € 10 in 1996 now only costs € 6.17 in 2021. Due to legal requirements, automatic inflation adjustments for pharmaceuticals are not permitted. Otherwise, the price of a fictitious drug packaging would be € 17.02 today.

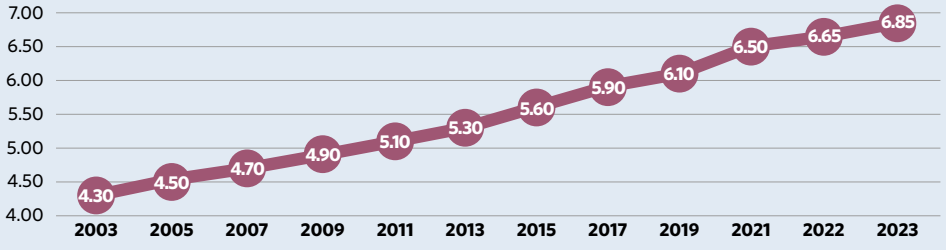
The divergence between consumer price index and pharmaceutical price index continues year to year. Prices for pharmaceuticals are falling continuously, while the consumer price index is rising annually.

In 2022, 44 % of all reimbursable* drug packages (measured by volume in units) were below the prescription fee of € 6.65 due to price adjustments.

* Refundable market: IQVIA DPMÖ next level with adapted data acquisition (incl. RX direct business) without selected non-refundable ATC 3 classes G03A, G40E, J07B/D/E, V01A, with non-prescription refundable products

The annual adjustment of the prescription fee is regulated by law and has increased between 2003 and 2023 by approximately 61 %. The earnings from prescription fees generated income of € 434 million for health insurance in 2021.

Development of prescription fees 2003–2023



Values in € million

Source: BMSGPK

In addition to a general exemption from the prescription fee for social reasons, since January 2008 there has been an annual prescription fee cap of 2 % of the insured person's annual net income (excluding special payments such as holiday or Christmas bonuses). As of the date on which this limit is exceeded, insured persons and co-insured relatives are exempt from the prescription fee for the rest of the calendar year.

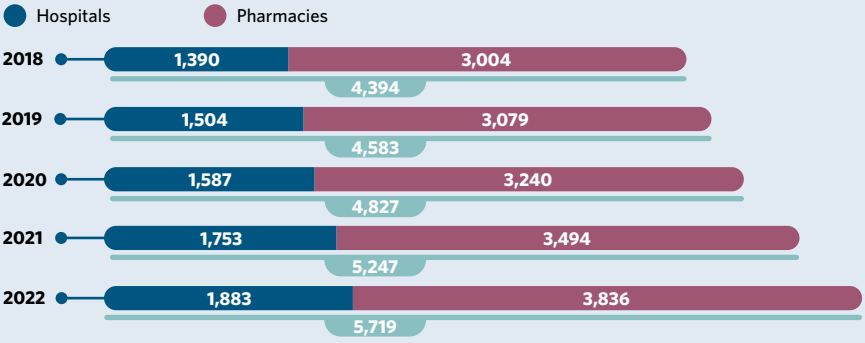
9.2 Hospital and pharmacy market

In 2022, the Austrian pharmaceutical market reported sales of € 5.7 billion and a sales volume of 239 million packages. Its growth therefore equals +9 % by sales and +8.5 % by 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 manufacturer price, MP*)



*Not taking discounts and refunds into consideration | Values in € million

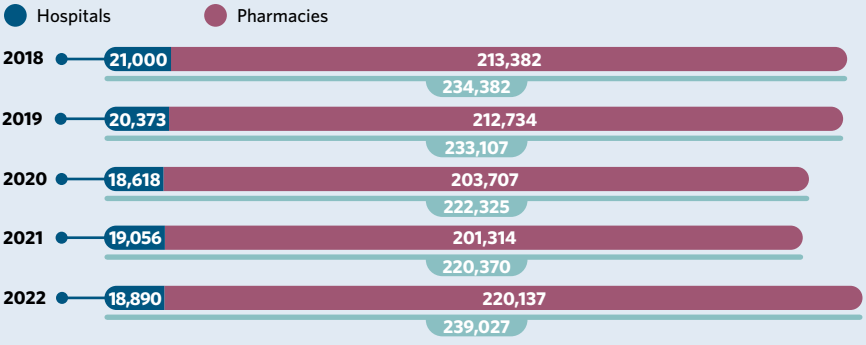
Source: IQVIA DPMÖ next level with adapted data source (incl. RX direct to pharmacy business)/DPMÖK

In 2022, compared to 2021, both the pharmacy and hospital market have grown in terms of value. In terms of volume, the hospital market is declining.

- **Pharmacy market:** +9.8 % regarding value according to euro in turnover or +9.4 % regarding volume according to packages
- **Hospital market:** +7.4 % regarding value according to euro in turnover or -0.8 % regarding volume according to packages

In 2022, 239 million packages were sold in Austria. Around 8 % of these went to hospitals (hospital pharmacies) and around 92 % to pharmacies in the extramural sector.

Sold packages



In units of 1,000

Source: IQVIA DPMÖ next level with adapted data source (incl. RX direct to pharmacy business)/DPMÖK

In 2022 vs. 2021 the number of sold packages increased by +8.5 %.

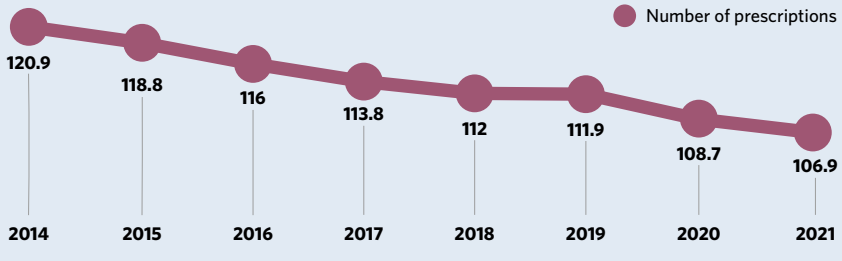
The growth of the established prescription market in the amount of +9 % (in terms of sales in 2022) is influenced by several factors, according to IQVIA's calculations:

- **Price changes** are changes in the price of a specific product that has already been launched on the market compared with the price of the previous period. In 2022 there were no price changes.
- **New launches** include those products that contain new active substances, in the first year after market launch. These products replace existing therapies or enable new drug therapies for the first time. In 2022, new launches influence market growth to a minor extent of +0.4 %.
- **Structural effects** include factors such as changes in prescribing habits, replacement and expansion of previous forms of therapy, new dosage forms, volume increases, and much more. In 2022, the structural effects amount to +8.6 %.

9.3 Prescription trends

The number of prescriptions has declined since 2015. In 2021 compared to 2014, it has decreased by approximately 11.4 %.

Number of reimbursed prescriptions

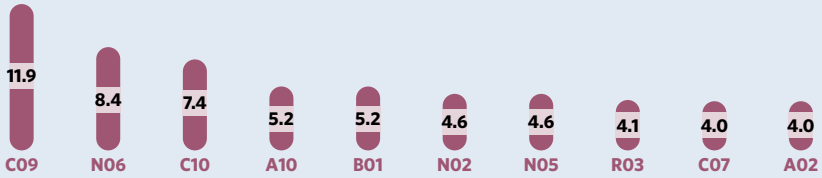


Values in € million

Source : SV

9.4 Pharmaceutical consumption by indication groups

The most frequently prescribed therapeutic subgroups ATC-level 2*, 2021



*ATC Code: Anatomical Therapeutic Chemical Classification System of the WHO
numbers in millions

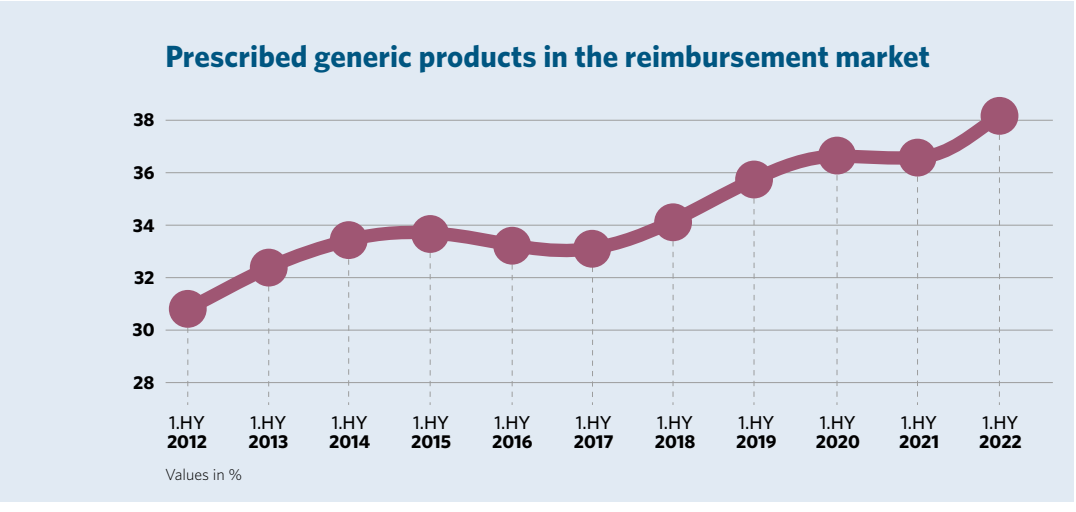
C09 Medicine for treating the renin-angiotensin system (e.g. with high blood pressure, chronic cardiac insufficiency)
N06 Psychoanaleptics (treatment of psychological illnesses such as depression, dementia, ADHD)
C10 Lipid lowering medicine (to counter metabolic disorders, e.g. with high cholesterol levels)
A10 Anti-diabetics (medicine against diabetes)
B01 Antithrombotic agents (inhibits clotting)
N02 Analgesics (pain medication)
N05 Psycholeptics (for treatment of psychotic illnesses such as psychosis, schizophrenia, medication for the treatment of sleep and anxiety problems)
R03 Agents for obstructive respiratory diseases (e.g. bronchial asthma, chronic lung disease/COPD, etc.)
C07 Beta-adrenoreceptor antagonist medication (e.g. for high blood pressure, cardiac insufficiency, angina pectoris)
A02 Medicine for the treatment of acid complaints (for neutralising stomach acid, e.g. with heartburn, acid indigestion)

Source: SV

Approximately 55 % of all prescriptions account for the top 10 indication groups with the highest number of prescriptions.

The most frequently prescribed medications according to the ATC system are: Medicinal products for the treatment of the renin-angiotensin system (e.g. with high blood pressure), psychoanaleptics (for the treatment of psychological illnesses, e.g. depression) as well as agents which influence lipid metabolism. These 3 indication groups with the highest prescription volume account for around 29 % of all prescriptions.

9.5 Generics in the reimbursement market



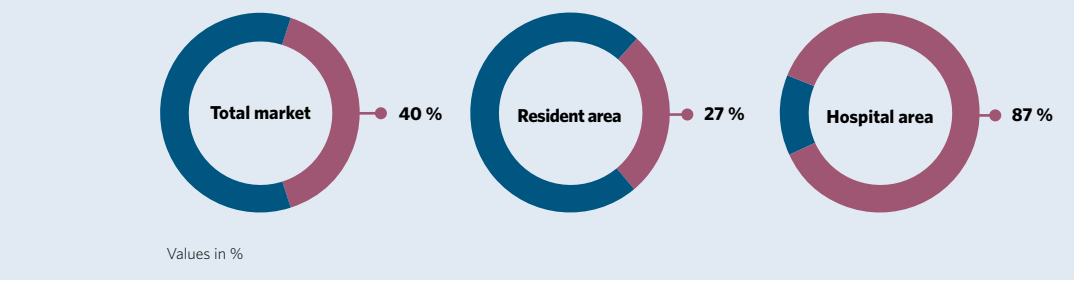
Source: SV

The prescription share of generics in all dispensed packages on the established prescription market is just under 40 % in 2022 (source: SV 2022). If we consider only the substitutable market, the share of generics is 54 %, i.e., more than every second dispensed package is a generic (source: SV 2021) (see chapters 4.1, 10.3).

9.6 Biosimilars

In Austria, 53 approved biosimilars (for 16 different active substances) are available for the treatment of serious diseases such as cancer, autoimmune diseases, growth disorders, osteoporosis, or blood coagulation (EMA approvals: 77 with 20 ingredients, status 2023).

40 % of the total biosimilar-eligible market in Austria (in terms of sales) is accounted for by biosimilars in 2022: in the retail market, this share is around 27 % and in the hospital market 87 %.



Source: IQVIA Biosimilarsverband Österreich, 2022

In Austria, the generics and biosimilars pricing rule also leads to significant price reductions for the original supplier (see chapters 4.1, 10.3).

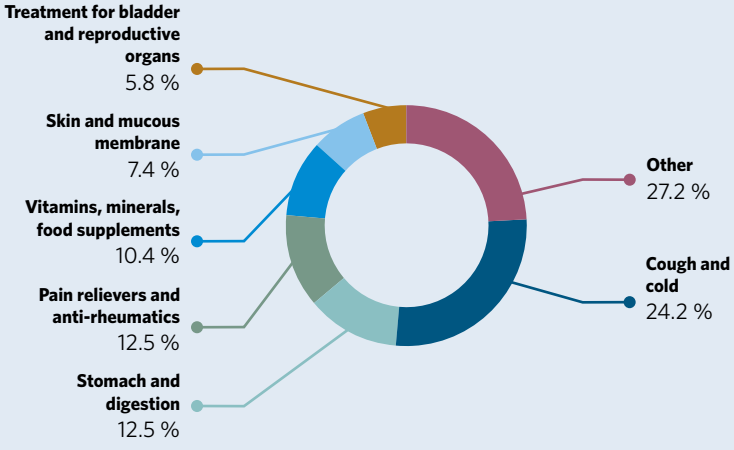
9.7 Self-medication market

In terms of value, the OTC market grew by +10.4 % to € 1.380 million (AVP) in 2022 compared to 2021. In terms of volume, there is also a positive development of +9.4 % in the OTC market; both sales and volume show a significant increase compared to 2021 and 2020.

The mail order share of the pharmacy market decreased from 15.6 % in 2020 to 115.8 % in 2021 (source: IQVIA on behalf of IGEPHA www.igepha.at and AUSTROMED www.austromed.org) – see distance-selling in chapter 8.3

Agents for the treatment of coughs and cold continue to represent the largest indication group in 2022 with a share of 24.2 % (measured in terms of sales in AVP). The growth rate compared to 2021 is +56 %, which is also due to the strong flu and cold waves.

Indication groups in self-medication (based on pharmacy sales price) in 2022



Values in %

Source: IGEPHA/IQVIA

Drugs in self-medication, so-called "over the counter" drugs (OTC), are effective, safe and make good health economic sense. They are therefore an integral part of health care and therapy for many diseases. About every fourth drug dispensed in pharmacies in Austria is such a prescription-free OTC drug.

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The reimbursement code (EKO) represents a

“whitelist”

and enables drugs to be prescribed in compliance with defined rules.

The listed products undergo a pharmacological, a medico-therapeutic and a health economic evaluation and convince due to

benefits and costs.

10. Pharmaceuticals reimbursement through social insurance

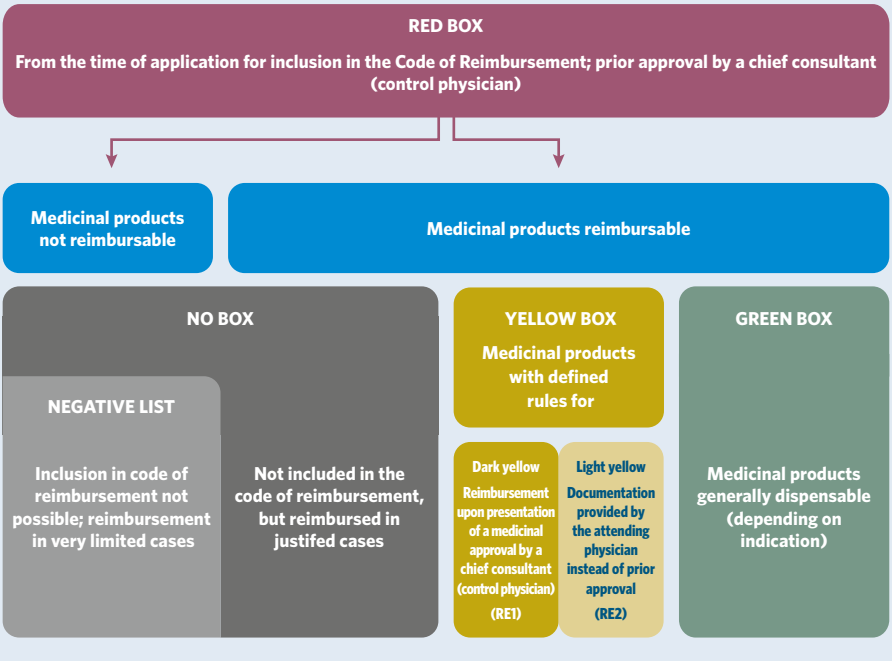
The principle of benefits in kind prevails with regard to the overwhelming number of benefits provided by social insurance institutions. The scope of medical treatment at the expense of social insurance is defined by law as follows: "It must be sufficient and purposeful but shall not go beyond what is necessary." (§ 133 ASVG)

10.1 Reimbursement Code (EKO)

The ASVG governs access to medicinal products for all insured persons in Austria in accordance with authorisation by social insurance. The Reimbursement Code (EKO) represents a "whitelist" and thereby enables either the "free prescription" (without prior approval by the chief & control physician service = **Green Box**) or defines rules (specific use – "regulatory text") for approval by chief & control physicians (**Yellow Box** of the EKO). The products listed in the EKO undergo a pharmacological, a medico-therapeutic and health economic evaluation (see chapter 10.2) – they convince by means of their benefits as well as with regard to the costs. As of Jan. 1, 2005, the Reimbursement Code (EKO) replaces the list of therapeutic products used until then.

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

The box system – simplified presentation



Source: PHARMIG

- **The Green Box** comprises medicinal products which are either generally 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 EKO are complied with. The comparator products listed in this box are relevant for price determination. If a higher price is targeted for the requested proprietary medicinal product, an added therapeutic value must be proven.

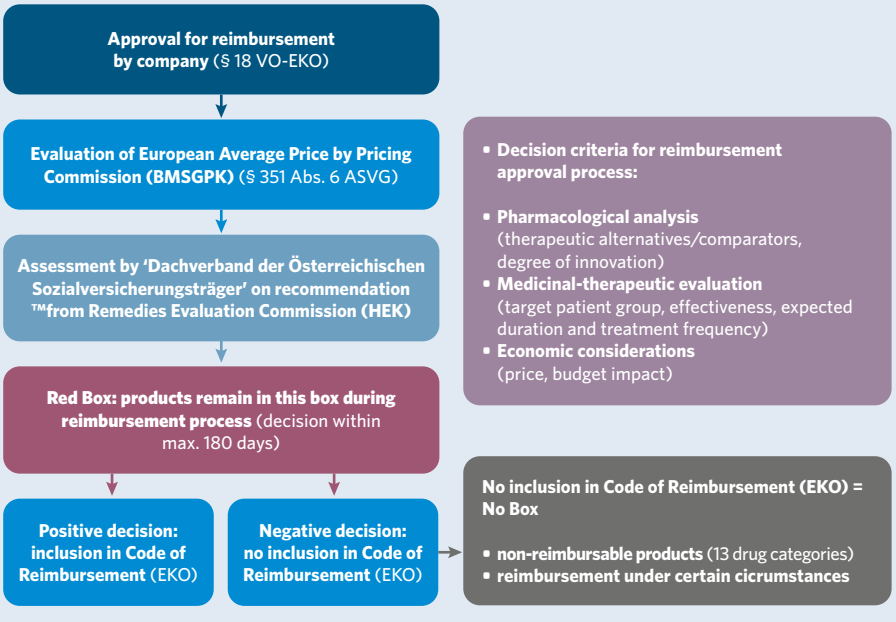
- **The Yellow Box** includes all those medicinal products which exhibit an essential additional therapeutic benefit for the patient and which are not included in the green area for medical and/or health-economic reasons. At most the determined EU average price may be offset for a proprietary medicinal product in this box. 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, the inclusion of which relates to a specific application, the "Dachverband der österreichischen Sozialversicherungsträger" 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 EKO was submitted. The price of the proprietary medicinal product may not exceed the EU average price. 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 EKO are only reimbursed in justified cases and upon presentation of the medical approval by a chief consultant (control physician). Authorisation must occur via the Pharmaceutical Authorisation Service (ABS). Before a contracted physician is allowed to prescribe medicinal products which are subject to authorisation to their patients, they must submit an electronic request to the chief & control physician service of the health insurance institution.

10.2 Approval for inclusion in the reimbursement process (VO-EKO in accordance with § 351 ASVG)

Based on ASVG (§ 351c ff.), the rules of procedure out of the publication of the Code of Reimbursement (VO-EKO) govern in detail the process, the prerequisite, and the deadlines for inclusion of medicinal products in the EKO. The inclusion procedure is an administrative procedure and takes place via electronic application. The publication of the medicinal products included in the Code of Reimbursement is always available in printed form at the beginning of the year. The monthly changes are published on the internet www.ris.bka.gv.at.



Source: PHARMIG

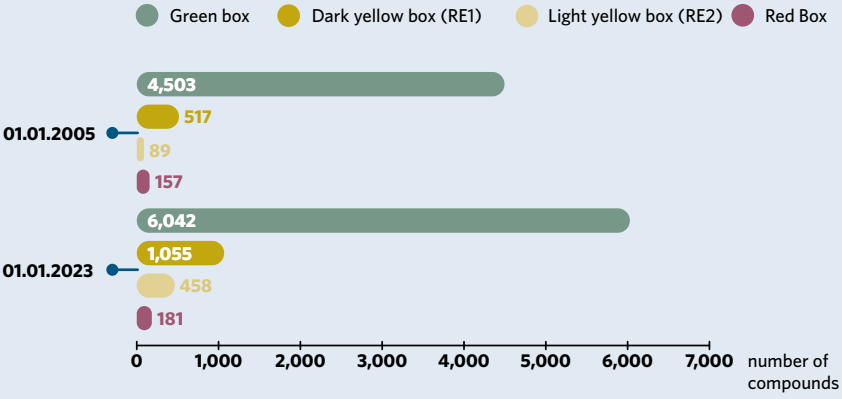
Specific groups of medicinal products are fundamentally excluded from inclusion in the EKO (Official Bulletin No. 34/2004: List of non-reimbursable medicinal product categories pursuant to § 351c Para.2 ASVG) and as a rule must be paid by patients themselves, unless the absorption of costs has been approved by the chief medical officer in advance (e.g. drugs that are primarily dispensed in hospitals, contraceptives etc.).

Remedies Evaluation Commission (HEK [Heilmittel-Evaluierungs-Kommission])

The Remedies Evaluation Commission is the advisory body of the 'Dachverband der Österreichischen Sozialversicherungsträger' (DV). All applications for inclusion (including amendments) of a medicinal product in the reimbursement codex must be submitted to the HEK. The HEK must also be heard if the DV intends to make a change in the EKO on its own initiative. The HEK makes a written recommendation to the DV.

Members of the Remedies Evaluation Commission or their representatives.
www.sozialversicherung.at

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



The data were taken from the list of goods published by the Austrian Chamber of Pharmacists | as of 01.01.2023
* by the package – pharmaceutical registration numbers

Source: WVZ

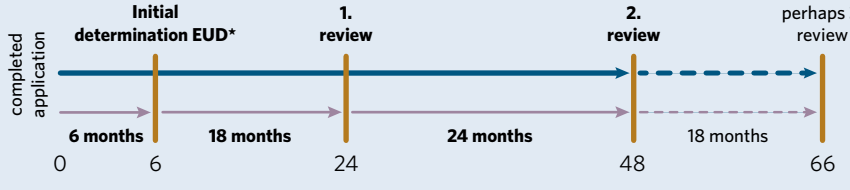
As of January 1st, 2023, a total of 7,736 packages were listed in the EKO. There were 5,266 packages upon its introduction in 2005.

10.3 Special price regulations through social insurance

European average price

The EU average price as a maximum limit for reimbursement prices was newly regulated during the 61st amendment of the General Social Insurance Act (ASVG). The Pricing Committee determines the EU average price from the prices reported by companies based in EU member states. As long as the EU average price cannot be determined (the EU average price is determinable if the MP/DSP is available in at least 2 member states of the EU, excluding Austria), the price reported by the authorised pharmaceutical company applies provisionally.

The EU average price is to be determined by the Pricing Committee within 6 months after application. The health institution known as Gesundheit Österreich GmbH (GÖG) can be consulted. After the first price determination, the Pricing Committee must once again determine an EU average price after 18 months and after another 24 months. A further determination is possible after another 18 months.

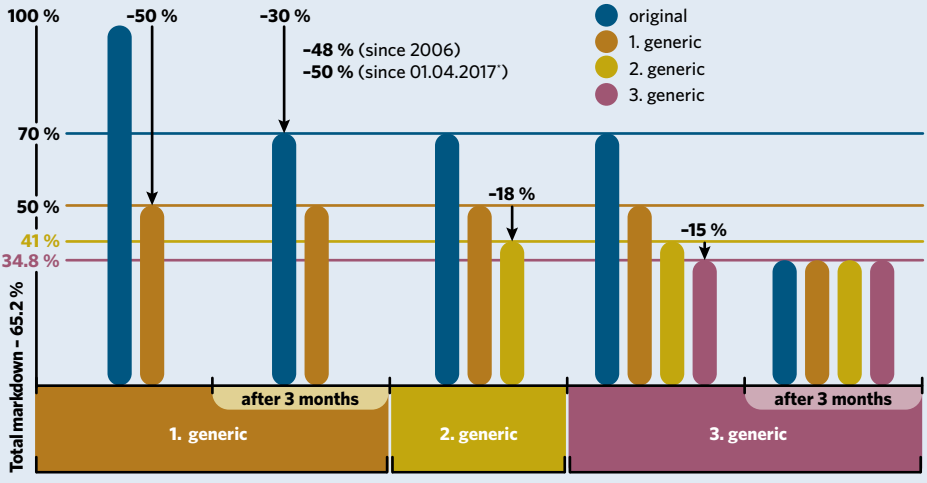


*EUD = EU average price

Source: PHARMIG

Generics

The previous price regulation was adapted with the 2017 amendment of the ASVG (Federal Law Gazette [BGBl.] I 49/2017; § 351c Para. 10 Z1 ASVG, see chapter 4.1 in regards to generics) for the inclusion or the continuance of interchangeable products with identical active substances (original and successor products):

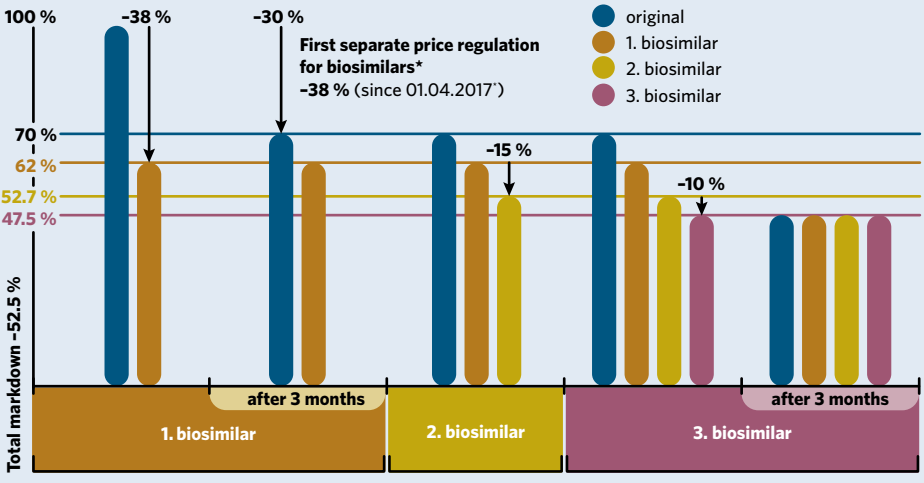


*ASVG amendment from BGBl. No. I, 49/2017 § 351c Para. 10 in force as of 1 April 2017, limited until 31 December 2023

Source: ASVG/VOEKO/Economic Evaluation Criteria of the Medicinal Products Evaluation Commission (HEK)

Biosimilars

A separate price regulation for biosimilars was specified in the ASVG with the 2017 amendment of the ASVG (§351c Para. 10 Z2 ASVG see chapter 4.1 with regard to biosimilars), with which the predictability of the market entry is facilitated:



*ASVG amendment from BGBl. No. I, 49/2017 § 351c Para. 10 in force as of 1 April 2017, limited until 31 December 2023

Source: ASVG/VOEKO/Economic Evaluation Criteria of the Medicinal Products Evaluation Commission (HEK)

"Price range" (the so called "Preisband")

Due to price divergences of individual active ingredients within the Green Box, a price range was established for the purpose of alignment in 2017, 2019 and 2021. The price of the affected medicinal products with the same active ingredient in the Green Box may not exceed the price of the cheapest medicinal product with the same active ingredient by more than 30 % on the reference date (February 1st of the respective review year) (ASVG amendment 2017, Section 351c (11)). In turn, cancellation procedures for those products will be eliminated until April 1st, 2022, for economic reasons.

In 2023, again a new, adopted application will be implemented, with a corridor of 20 % to the cheapest drug speciality with the same active ingredient in the same or practically the same dosage form. The relevant strength within an active ingredient is the respective key strength (the most frequently prescribed). The price reduction is necessary to a maximum of the prescription fee, i.e. drug specialties with a price charged to the social insurance below the prescription fee are excluded from this regulation. However, these are used to determine the maximum price. In return, there will be no cancellation procedures for these products until December 31st, 2023, for economic reasons.

According to social insurance, the savings from the implementation of the price band in 2017, 2019 and 2021 amounted to approximately € 74 million (on the basis of the reimbursed price, KVP). In 2023, the savings are expected to amount to approximately € 101 million (on the basis of KVP), which will be available to the social insurance as investment.

Source: Response to Parliamentary Question 8908/AB, IQVIA

Special provisions for proprietary medicinal products outside of the EKO ("No Box")

The special provisions (Section 351c (9a) ASVG) that have been in force since the 2017 ASVG amendment for pharmaceutical specialties that are not listed in the EKO (see chapter 10.1) but are reimbursed in certain exceptional cases were tightened in 2022 (BGBL. 32/2022). For these pharmaceutical specialties, if annual sales exceed € 750,000, a partial amount must be repaid to the social insurance by the pharmaceutical companies. The price commission establishes the EU average price for these products as a benchmark. If the MP charged by social insurance exceeds the determined EU average price, a repayment obligation in excess of the difference arises for these pharmaceutical specialties.

Price increases

Price increases for pharmaceuticals are regulated by law in a very restrictive manner (e.g. max. every 24 months) and are only possible to a very limited extent. The 'Dachverband der österreichischen Sozialversicherungsträger' has a wide margin of discretion in this regard.

In 2022, 116 applications for price increases were submitted by manufacturers for the approximately 7,600 packages listed in the reimbursement code. 90 applications actually resulted in price increases. This resulted in 91 packages with price increases. In comparison: In the same time period, there were price reductions for 822 packages within the Reimbursement Code.

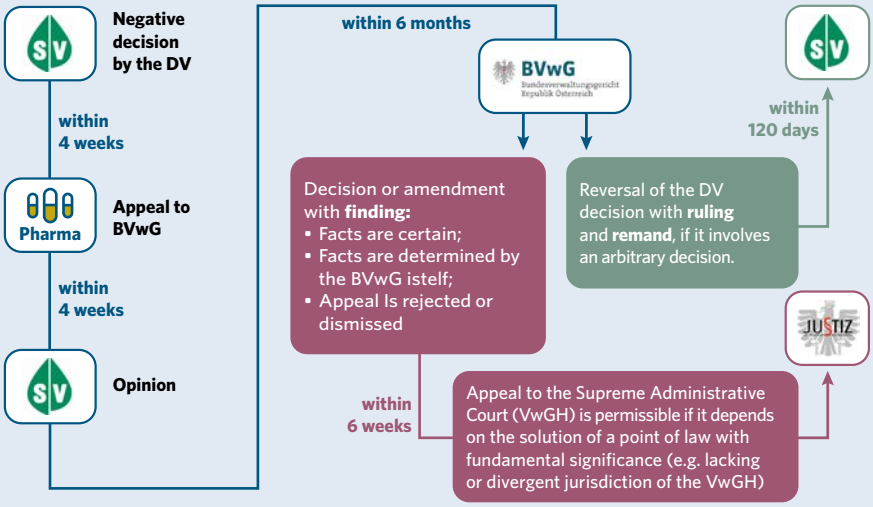
Source: EKO, parliamentary inquiry response; PHARMIG.EKO, parlamentarische Anfragebeantwortung, PHARMIG

10.4 Federal administrative court

The Federal Administrative Court is competent for appeals against a decision of the 'Dachverband der österreichischen Sozialversicherungsträger'. An appeal must be submitted within 4 weeks after the decision has been served via the internet portal www.sozialversicherung.at.

The appeal has a suspensive effect. The decision is made by a 5-member senate (deliberation and voting of the senate not public). The findings of the Federal Administrative Court (BVwG) are published in the Legal Information System of the Federation (RIS) – www.ris.bka.gv.at.

Process flow



Source: Dr. Martin Zartl, Bayer Austria Ges.m.b.H.

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Since 1970,

the PHARMIG CoC has included industry-wide compliance regulations.

In addition to

general principles,

binding regulations are laid down for information on medicinal products and advertising measures, as well as for transparent cooperation with doctors and patient organisations.

11. PHARMIG Code of Conduct (CoC)

Pharmaceutical companies develop, produce and sell medicinal products. They are also responsible for updating doctors, pharmacists, patients and the general public about their medicinal products, and so to contribute to the safety as well as the correct use of the pharmaceutical products. In this context, the exchange of the respective experience is an essential aspect, which also flows into the further development of therapy concepts. All these aspects require a reasonable basis for the cooperation of several partners in the health care system. In this context, it is important to focus on the respective scientific context when collaborating with health care professionals or institutions and to design the framework for the collaboration in a comprehensible and transparent manner.

This is precisely where industry-wide compliance regulations come in: the pharmaceutical industry did pioneering work in this area. The CoC has been making a valuable and important contribution since 1970: The regulations specify that legal requirements are complied with, that the freedom of procurement, decision-making and therapy of health care professionals is not unfairly influenced, and that ultimately this strengthens the confidence of the public and patients in the necessary cooperation.

The PHARMIG Code of Conduct (CoC) codifies, in addition to the basic principles, binding rules for information about medication and advertising tactics. It comprehensively regulates the collaboration between pharmaceutical companies and doctors, institutions such as hospitals or expert associations, and patient organisations. The aim is to make this cooperation fair and transparent.

The pharmaceutical companies that have submitted to the CoC demonstrate a high sense of responsibility and set a clear example of integrity. To fulfil this responsibility, compliance advisors exist, which support the companies from within as business partners of integrity.

Companies live ethical responsibility

Compliance is the responsibility of all employees and business units and primarily concerns:

- promoting **ethical** and **legally compliant behaviour** between the **pharmaceutical industry, business partners** (such as health care professionals) and **stakeholders**
- ensuring **fair competition** within the **pharmaceutical industry**
- ensuring that physicians are informed about therapeutic options in an **objective** and **legally** compliant manner
- consistent **compliance** with the established principles of conduct and their monitoring
- **training** for **employees** and external **cooperation partners** regarding **ethical principles** and **anti-corruption regulations**
- **compliance programme** in all implemented departments to protect **integrity** of the **company**

Transparency creates trust

Since 2014, the CoC also contains provisions on how pharmaceutical companies disclose pecuniary benefits when they cooperate with for example physicians or hospitals or support the work of patient organisations. Essentially, the individual disclosure of pecuniary benefits resulting from this cooperation is to be aimed for. Individual disclosure must be based on data protection law. Depending on the situation, this may be consent or an overriding legitimate interest. In the event that this is not the case, disclosure shall be made in aggregated form. Disclosure is made annually as of June 30th on a publicly accessible website. More information on the transparency initiative can be found at: 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 to embrace the high ethical standards of our branch. The Code of Conduct was introduced in 1970 and was last updated in 2020.

In order to be able to clarify differences of opinion regarding the CoC provisions quickly outside of court, in front of a panel of experts, it is possible to conduct a so-called CoC procedure in front of the CoC Committees of Experts of the 1st and 2nd instance.

Non-members and third parties also have the possibility to file complaints about alleged violations against the CoC. This is done by means of a written agreement that ensures that the parties to the relevant procedure are subject to the same rule. Under certain circumstance, the complaints can also be filed anonymously.

In the interest of legal certainty, the results of the CoC-procedures are published in anonymised form on our website www.pharmig.at.

Flowchart – procedure of the CoC committees of experts of the 1st and 2nd instance:
www.pharmig.at

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12. 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
Ordinance on the Retail of Medicinal Products *Abgrenzungsverordnung*	Definition of pharmacies and drug stores as distribution channels
General Social Insurance Act *Allgemeines Sozialversicherungsgesetz (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.
Pharmacopoeia Act *Arzneibuchgesetz (ABG)*	Quality and testing of medicinal products
Medicinal Products Act *Arzneimittelgesetz (AMG)*	Definitions, clinical trials, marketing authorisation, manufacture, distribution, advertising, pharmacovigilance, approval of plant and equipment
Austrian Medicine Import Act *Arzneiwareneinfuhrgesetz (AWEG)*	Import and distribution of medicinal products
Federal Act against Unfair Competition *Bundesgesetz gegen unlauteren Wettbewerb (UWG)*	Advertisement with regard to consumers and competitors
Federal Hospitals Act *Bundesgesetz über Krankenanstalten und Kuranstalten (KAKuG)*	Forms the legal basis for all hospitals and the foundations for the 9 provincial laws, which represent implementation statutes
Federal Statistics Act *Bundesstatistikgesetz (BstatG)*	Provision of data by the federal government to certain recipients; regulations on "Statistics Austria"; basis for the implementation of the Austrian Micro Data Center
Federal Procurement Act *Bundesvergabegesetz (BVergG)*	Governs the procedure for procurement of services (procurement procedure) in the public sector
Federal Administrative Court Act *Bundesverwaltungsgerichtsgesetz (BVwGG)*	Governs the organisation of the Federal Administrative Court
EU Community code relating to medicinal products for human use (Directive 2001/83/EC)	Definitions, marketing authorisation and procedures, manufacturer, and importation, labelling and package leaflet, wholesaling, advertising and information, pharmacovigilance

Law	Scope of applicability
EU Delegated Regulation on safety features (Delegated Regulation 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
EU Council Directive on Transparency in Pricing (Directive 89/105/EEC)	Procedural provisions, timelines and transparency rules for national decisions regarding reimbursement and prices
Summary of Product Characteristics Ordinance *Fachinformationsverordnung*	Structure of the SPC (Summary of Product Characteristics)
Research Organisation Act *Forschungsorganisationsgesetz (FOG)*	Support of science and research; framework conditions for data processing for the purpose of research and statistics; access to register data for operational research
Health and Food Safety Act *Gesundheits- und Ernährungssicherheitsgesetz (GESG)*	Spin-off of responsibilities and procedures regarding the medicinal product system from the Federal Ministry for Health to the Austrian Medicines and Medical devices Agency
Ordinance on Distance Selling *Fernabsatz-VO*	Sales of medicinal products via distance selling
Ordinance on Package Leaflets *Gebrauchsinformationsverordnung*	Structure of Package Leaflet (PL)
Ordinance on the Authorisation and Control of Medicinal Products *Heilmittel-Bewilligungs- und Kontroll-Verordnung (HBKV)*	Ordinance setting forth the principles of approval of medicinal products by chief consultants and control physicians, follow-up control of prescriptions and documentation principles
Ordinance on the Labelling of Products *Kennzeichnungsverordnung*	Structure of labelling/outer packaging
Patent Protection Act *Patentgesetz (PATG)*	Patent protection also of medicinal products
Price Act *Preisgesetz*	Pricing and (by ordinances) maximum mark-ups
Prescription Act *Rezeptpflichtgesetz*	Prescription status
Narcotic Substances ordinance *Suchtgiftverordnung (SV)*	Distribution of narcotic-containing medicinal products
Narcotic Substance Act *Suchtmittelgesetzt (SMG)*	Narcotics status, charges and placing on the market

Law	Scope of applicability
Pharmacovigilance Ordinance *Pharmakovigilanzverordnung*	Pharmacovigilance responsibilities of the marketing authorisation holder, notification of side effects and incidents
Ordinance on pharmaceutical representatives *Pharmareferentenverordnung*	Authorisation and testing of pharmaceutical representatives
Ordinance on Non-Interventional Studies (NIS) *Verordnung über die Meldepflicht für nicht-interventionelle Studien* (Repealed as of 07.10.2022)	Compulsory registration of non-interventional studies before implementing (since 01.09.2010); includes preparation, planning, inspection, authorisation of non-interventional studies; relevant for pharmaceutical companies who plan, implement, audit or finance a NIS
Rules of procedure for the publication of the Reimbursement Code 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
Administrative Court Procedural Act *Verwaltungsgerichts-verfahrensgesetz (VwGVG)*	Governs the procedures at the Federal Administrative Court

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 patient organisations
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

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13. Abbreviations

Abbreviation	Explanation
AGES	Agency for Health and Food Safety | Agentur für Gesundheit und Ernährungssicherheit
AMBO	Regulation on Operating Instructions for Medicinal Products
AMG	Austrian Medicinal Drugs Act
AMDC	Austrian Micro Data Center
AMVO	Austrian Medicines Verification Organisation
AMVS	Austrian Medicines Verification System
ASVG	General Social Insurance Act | Allgemeines Sozialversicherungsgesetz
AVP	Pharmacy retail price
BASG	Federal Office for Safety in Health Care | Bundesamt für Sicherheit im Gesundheitswesen
BGBl.	Federal Law Gazette | Bundesgesetzblatt
BMGF	Federal Ministry for Health and Women until 7.1.2018 | Bundesministerium für Gesundheit und Frauen bis 07.01.2018
BMSGPK	Federal Ministry of Social Affairs, Health, Care and Consumer Protection | Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz
BVwG	Federal Administrative Court
c4c	Connect for Children
DCP	Decentralised Procedure | Dezentrales Verfahren
DTP	Direct to Pharmacy | Direktlieferung
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHDS	European Health Data Space
EKO	Reimbursement Code | Erstattungskodex
EMA	European Medicines Agency | Europäische Arzneimittelagentur
EMVO	European Medicines Verification Organisation
Enpr-EMA	European Network of Paediatric Research at the European Medicines Agency
R&D	Research & Development

Abbreviation	Explanation
GESG	Health and Food Safety Act | Gesundheits- und Ernährungs-sicherheitsgesetz
GDP	Gross domestic product
GMP	Good manufacturing practice
HEK	Medicinal Products Evaluation Commission | Heilmittel-Evaluierungs-Kommission
HTA	Health Technology Assessment
ICD-10	International Classification of Diseases and Related Health Problems
IGEPHA	The Austrian Self-Medication Industry | Interessengemeinschaft österreichischer Heilmittelhersteller und Depositeure
IPF	Institute of Pharmaco-economic Research | Institut für Pharmaökonomische Forschung
IQVIA	IQVIA Marktforschung GmbH
KVP	Box office price
LKF	Performance-oriented Hospital Financing
m., b.	Million(s), Billion(s)
MRP	Mutual Recognition
NIS	Non-interventional study
OECD	Organization for Economic Cooperation and Development
OKIDS	Child Research Network
ÖVIH	Austrian Vaccine Manufacturer Association
OTC	Over The Counter
PedCRIN	Paediatric Clinical Research Infrastructure Network
PHAGO	Austrian Association of Full-Line Pharmaceutical Wholesalers
PIP	Paediatric Investigation Plan
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QP	Qualified Person

Abbreviation	Explanation
SHA	System of Health Accounts
SPC	Supplementary Protection Certificate
SV	Main Association of Austrian Social Insurance Institutions
CoC	Code of Conduct
VO	Ordinance
VO-EKO	Ordinance on the code of Reimbursement (EKO) according to § 351g ASVG
WHO	World Health Organization

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notes

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PHARMIG

Association of the Austrian
Pharmaceutical Industry