Facts & Figures 2024

Pharmaceuticals and Healthcare in Austria

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PHARMIG
Association of the Austrian Pharmaceutical Industry

Imprint

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Content

PHARMIG at a glance

PHARMIG – The Association of the Pharmaceutical Industry of Austria is a voluntary, politically independent organization representing the interests of the pharmaceutical industry in Austria. PHARMIG represents about 120 companies with approx. 18,000 employees, covering around 95 % of the domestic pharmaceutical market.

PHARMIG and its member companies are committed to securing the supply of pharmaceuticals in the healthcare sector and ensuring social and medical progress through quality and innovation.

The pharmaceutical industry is committed to strengthening Austria as a research and pharmaceutical location. In doing so, it relies on intensive cooperation between businesses and the science sector, which ultimately serves the further development of knowledge in our society.

As a recognized and competent partner with a high level of expertise, PHARMIG supports decision-makers in the healthcare sector as well as relevant policy areas.

In doing so, PHARMIG calls for fair, reliable, and plannable conditions for the pharmaceutical industry, which in turn serve all stakeholders and the entire population.

The primary goal of the association and the entrepreneurial activity of the pharmaceutical industry is to ensure an optimal supply of medicines to the population in Austria.

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Dear Reader!

Reliable information is crucial in a time that is developing as dynamically as ours. It offers orientation and security and forms the basis for well-founded decisions.

It is with great pleasure that I present to you the current issue of Facts & Figures 2024. As usual, this publication provides you with comprehensive information on the Austrian healthcare system.

This way, we once again want to make a fact-based contribution to dialogue and joint discussion about current and future challenges in Austria as a healthcare and pharmaceutical location. In the current anniversary year of PHARMIG for the 41st time in the form of this publication.

For this issue, we have not only fully updated the statistical figures, but have also expanded Chapter 1.2 to include the presentation of social expenditure. In addition, Chapter 1.6 Structure and Financing of Healthcare has been expanded by the topic of the national evaluation board, which has taken shape in the course of the financial equalization negotiations.

To show the latest developments in the design of the European Health Data Space (EHDS) at the European level, chapter 4.7 Use of Health Data has been updated.

The Facts & Figures 2024 as well as selected graphics and the German version "Daten & Fakten 2024" are available to download on our website www.pharmig.at.

I wish you an exciting read and a lot of knowledge gained from our Facts & Figures 2024!

Kind regards,

Mag. Alexander Herzog
Secretary General, PHARMIG

approx. 52.6 billion

Euros were spent on healthcare in 2022
(equivalent to approx. 11.8 % of the national GDP)

76.3 % public

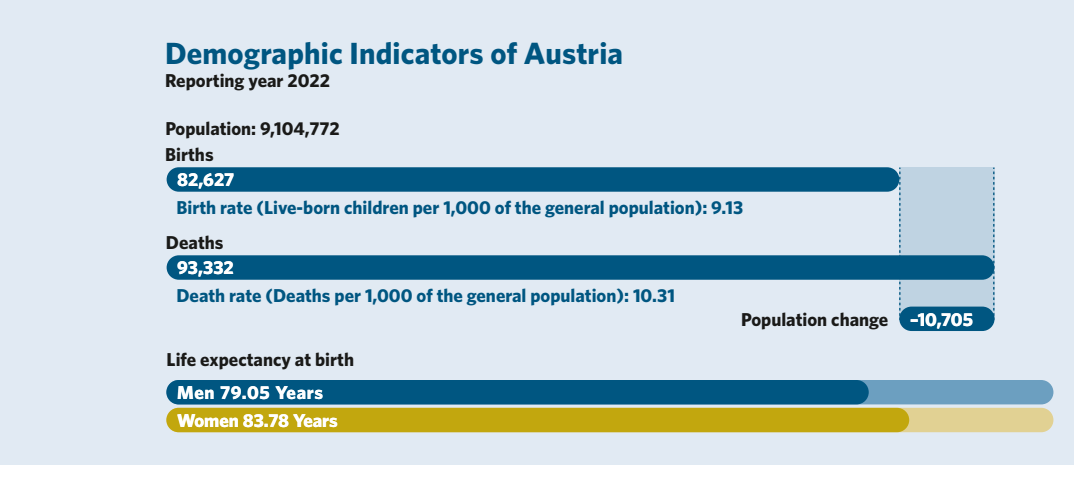
vs. 23.7 % private expenditure
(financing of the healthcare system)

1. Healthcare system in Austria

The Austrian healthcare system is characterized by the country's federalist structure. Due to the large number of decision-makers (federal, state, local, social security), the financing of healthcare is not centrally regulated and comes from various sources (such as taxes, social security contributions via social insurance, federal, state, local government, etc. – see Chapter 1.3). Due to the fragmented responsibilities, coordination among those responsible is essential. Important framework conditions are therefore laid down in joint agreements and treaties (e.g. agreements under Article 15a of the Federal Constitutional Act [B-VG]).

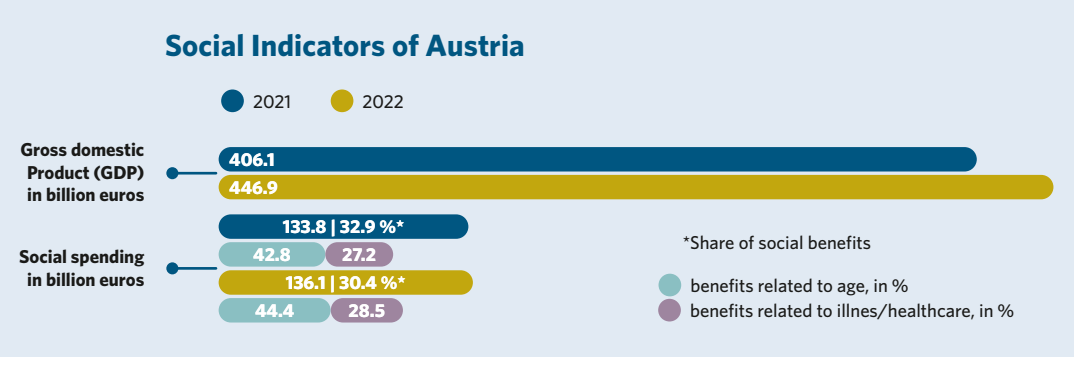
1.1 Key economic data

At the beginning of 2023, Austria's resident population numbered 9,104,772 people, 125,843 (+1.4 %) more than at the beginning of 2022. This increase is mainly due to the immigration of Ukrainian nationals (1).



Source: STATISTIK AUSTRIA, Demographische Querschnittsindikatoren (2.3)

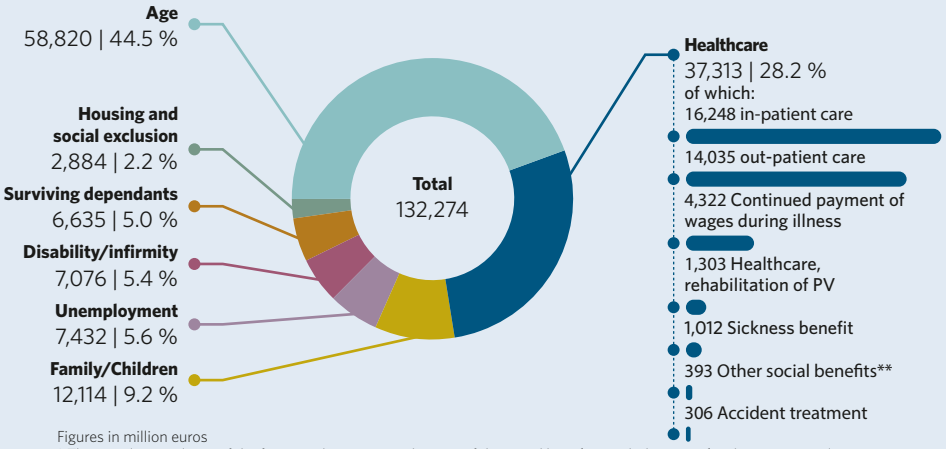
1.2 Social expenditure



Source: STATISTIK AUSTRIA, Sozialausgaben (4, 5)

In 2022, social spending in Austria amounted to 136.1 billion euros. Almost three-quarters of this was spent on age-related and healthcare benefits. The increase in spending compared to 2021 (+2 %) is mainly due to above-average allocations to other social benefits** at retirement age (58.8 billion euros, +4.9 %) and to healthcare (37.3 billion euros, +6.6 %). Due to significantly stronger economic growth of 10.0 %, the social ratio (share of social expenditure in nominal gross domestic product (GDP)) fell to 30.4 % (2021: 32.9 %) (4).

Social Expenditure* by Function 2022



Figures in million euros
* The social expenditure of the functional structure is the sum of the social benefits, excluding transfers between social security systems (diverted social contributions and other transfers) and excluding other expenditures.
** Accident treatment; Cash benefits from healthcare institutions, benefits in kind from social assistance/minimum income (data from 2000 onwards are only partially comparable with earlier ones)

Source: Statistik Austria: Sozialleistungsausgaben nach Funktion und Sozialleistung 1990 bis 2022, Jahressumme in Mio. Euro (6)

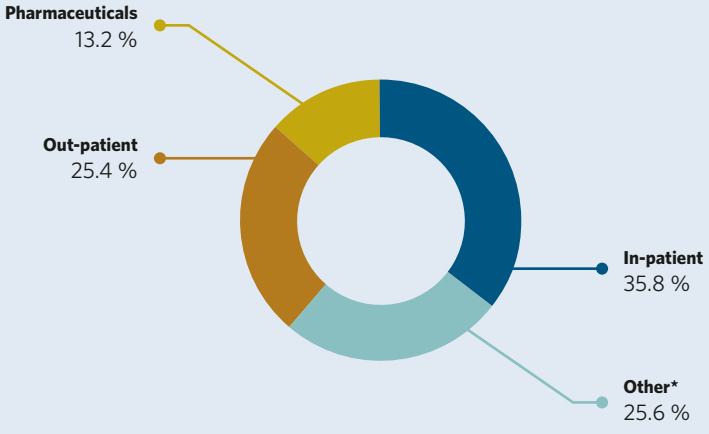
1.3 Health expenditure

According to the "System of Health Accounts" (SHA), health expenditure is made up of current health spending and investments in the health sector (7).

In 2022, total healthcare spending in Austria amounted to around 52.6 billion euros, which corresponds to a share of 11.8 % of the GDP. The ongoing health expenditure is estimated at 49.9 billion euros and a share of 11.2 % of the GDP (8). Compared to 2021, health expenditure increased nominally (at current prices) by 651 million euros or 1.3 %. Austria is thus in eighth place (9) compared to the 38 OECD countries :

- OECD average: 9.2 % of the GDP
- Average of the 22 EU Member States in the OECD: 9.1 % of the GDP
- Countries with the highest health spending compared to economic output: USA (16.6 %), Germany (12.7 %) and France (12.1 %).

Healthcare Spending by Setting 2022



* Spending on long-term care, patient transportation, public health services and prevention, administration, medical devices and equipment, private insurance

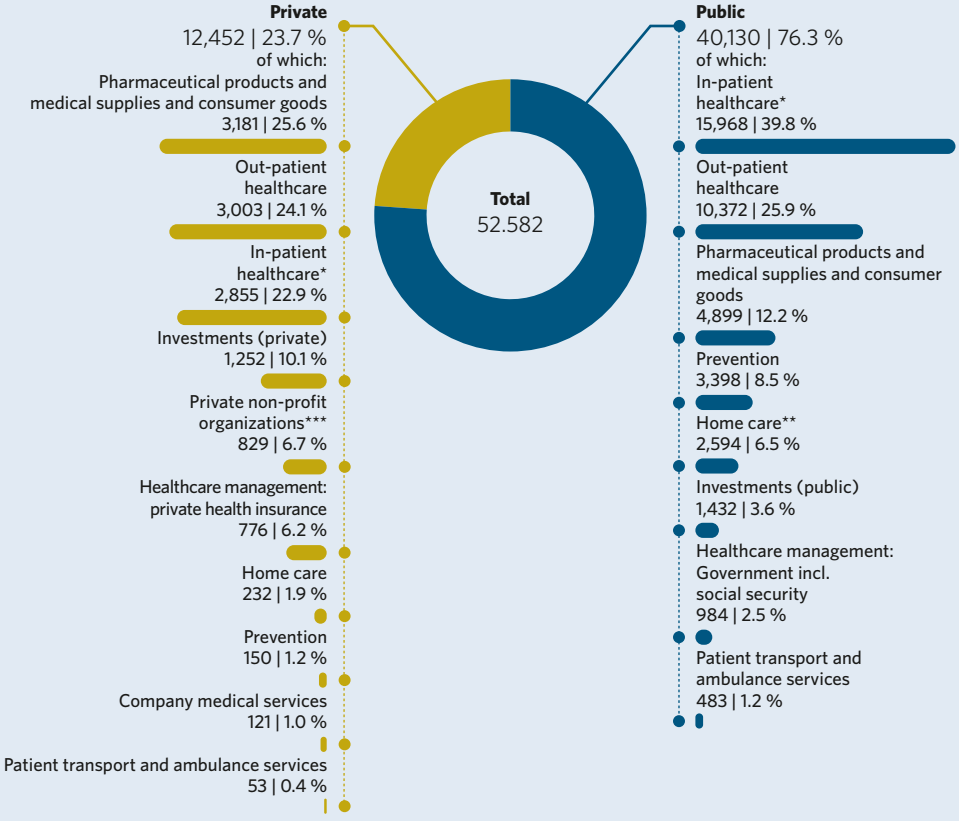
Source: berechnet durch das Institut für pharmaökonomische Forschung (IPF) unter Verwendung folgender Sources: IQVIA, Statistik Austria, SV

The largest share (35.8 %) was spent on the in-patient sector, while 25.4 % was spent on the out-patient sector and 13.2 % on pharmaceuticals.

Pharmaceutical expenditure includes consumption in the pharmacy and hospital markets, including VAT. The share of **pharmaceutical expenditure** in total health expenditure as a percentage is referred to as the pharmaceutical quota.
The pharmaceutical quota also reflects the nationally different importance of the settings in the healthcare system (in-patient, out-patient, medicinal).

Expenditure on "other" is again very high in 2022 at 25.6 %. This includes expenditure on long-term care, patient transport, public health services and prevention, administration, medical devices and equipment, and private insurance.

Healthcare Financing in 2022

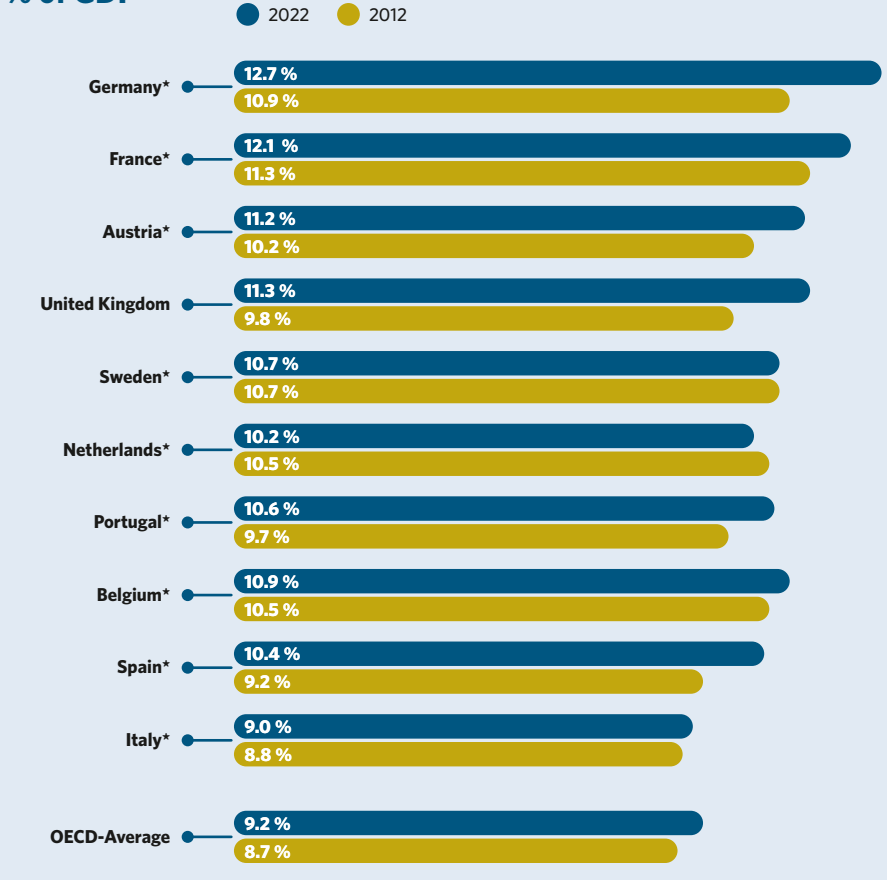


Figures in million euros | Percent
* Also including inpatient healthcare services in nursing homes.
** Public expenditure on long-term home care also includes the care allowance.
*** Including the private NPO's expenditure on emergency services and other health services.

Source: STATISTIK Austria - Gesundheitsausgaben (8)

Broken down into public and private health expenditure, more than three-quarters of expenditure is financed by public funds. The increase in expenditure compared to 2021 is mainly due to services to cope with the COVID-19 pandemic (expenditure on prevention).

Current Healthcare Spending – Comparison of Countries 2022 – % of GDP[1]



* preliminary value

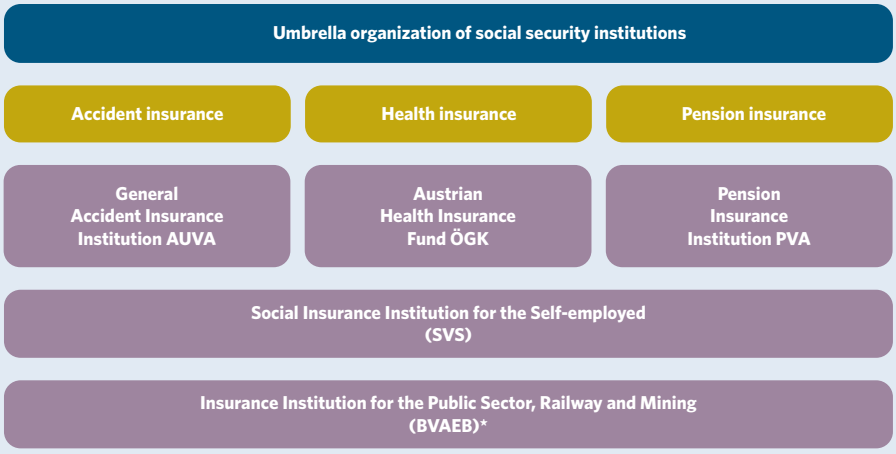
[1] Graphical representation of selected OECD countries

Source: Darstellung nach Daten von Health at a Glance 2023, OECD INDICATORS (10)

Due to national differences in healthcare systems and the different data availability and data collection in the listed countries, international comparisons are only possible to a limited extent.

1.4 Social Security Structure

Structure of Austrian Social Security



* incl. PV acc. to Federal Pension Office Transfer Act

Source: Österreichische Sozialversicherung, SV (11)

The current structure of social insurance, consisting of five insurance institutions and the superordinate umbrella organization, was introduced on 1 January 2020.

The Austrian social security system covers 99 % of the resident population and is based 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). Statutory health insurance allows multiple insurances.

With 7.5 million insured people (82 % of the Austrian resident population), the Austrian Health Insurance Fund is the largest statutory health insurance fund in Austria (12).

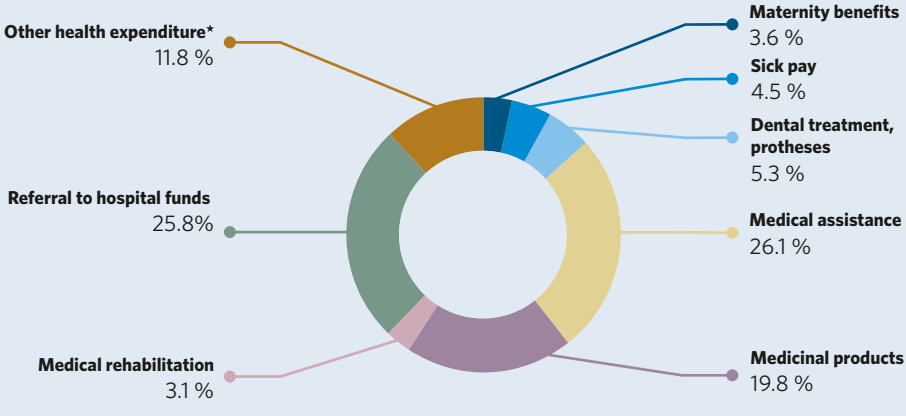
In addition to the statutory health insurance, there are 15 healthcare institutions (KFA [Krankenfürsorgeanstalten]) for the health insurance of employees in various state and municipal administrations.

1.5 Management of the health insurance institutions

In 2022, the revenue of the statutory health insurance institutions amounted to about 22.7 billion euros (+6.1 % compared to 2021), while expenditure amounted to 23.1 billion euros (+7.5 %). The negative result amounted to minus 411 million euros. 80 % of social security revenue was generated by insurance contributions, 13 % came from the Federal Government's default liability and a further 7 % was other income (13).

On an annual average in 2022, there were 8,942,791 eligible persons, of whom 4,420,872 were men and 4,521,919 women (14).

Spending of the Health Insurance Institutions in 2022



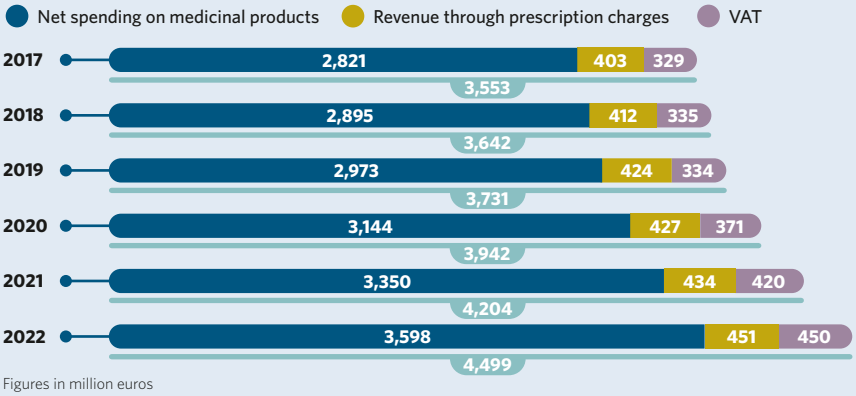
Figures as a percentage of total revenue
*Catering costs and other services; Sick pay, rehabilitation, etc.

Source: Statistisches Handbuch der österreichischen Sozialversicherung 2023 (14)

In 2022, the health insurance institutions covered the costs of 109 million packages of pharmaceuticals and spent 4.1 billion euros (excluding VAT) on them. Each insured person accounted for an average of 12 packages of medicines and expenses of 458 euros (14).

The expenditure item Medicinal products (gross) contains 10 % VAT and does not take the collected prescription fees into account. Net spending on medicinal products will also be reduced through individual discounts and repayments by pharmaceutical companies to social insurance (SV). These repayments significantly reduce the expenses of the SV and lead to a further reduction in its net expenses. The sum of rebates increases every year.

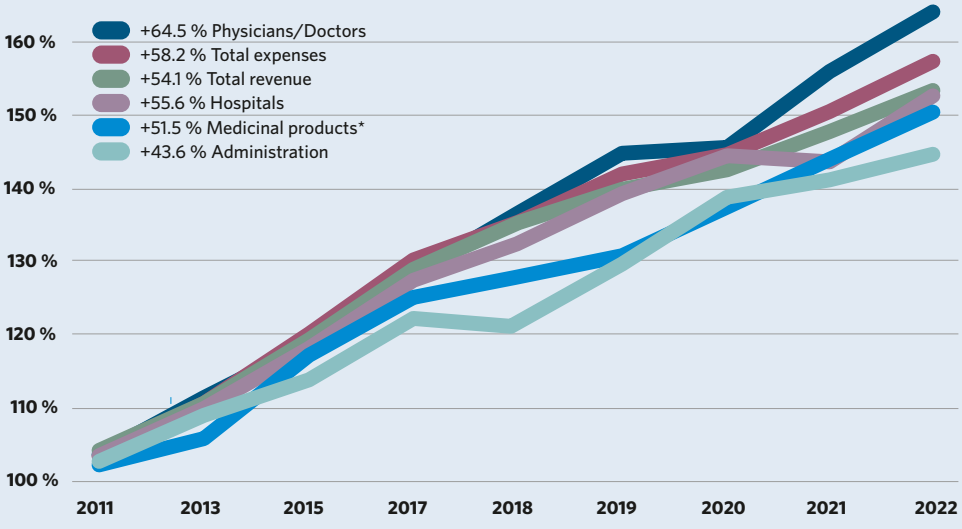
Spending on medicinal products



Figures in million euros

Source: Berechnung nach Angaben aus: Die österreichische Sozialversicherung in Zahlen (13)

Development of the Total Expenditures/ Total Revenues

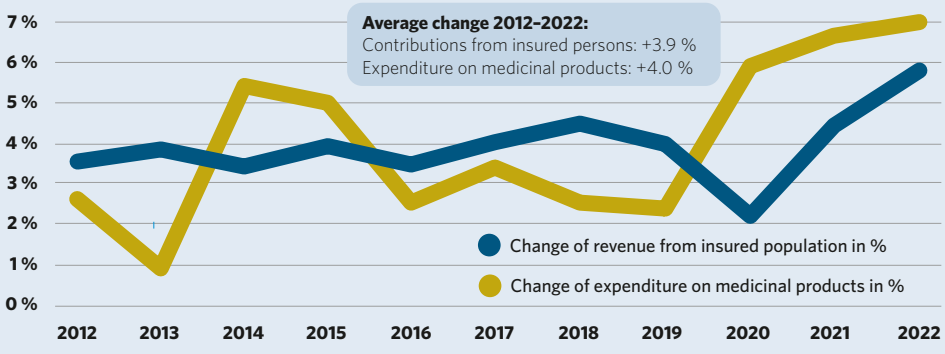


*Gross, incl. prescription charges, VAT, refunds and discounts

Source: Die Österreichische Sozialversicherung in Zahlen (13)

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

Development of Revenue from Contributions vs. Expenditure on Medicinal Products



Source: Statistisches Handbuch der Österreichischen Sozialversicherung (14)

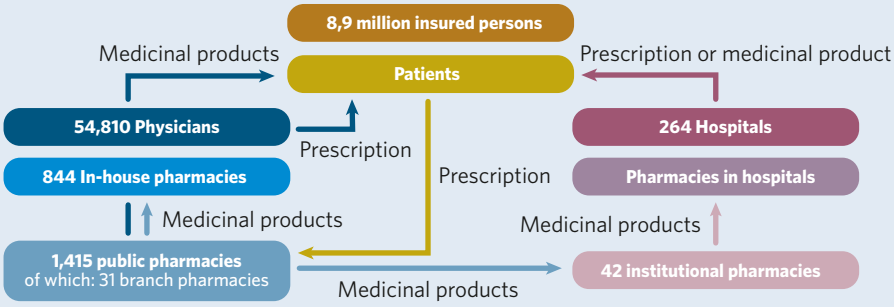
The income of the health insurance institutions from the contributions of all insured persons increased by an average of +3.9 % in the years 2012 to 2022. Over the same period, expenditure on therapeutic products increased by +4.0 % (excludes prescription fees collected and individual discounts and repayments from pharmaceutical companies) (14).

1.6 Structure and financing of healthcare

Austria has a dense network of medical care facilities. Patients have access to five different levels of care:

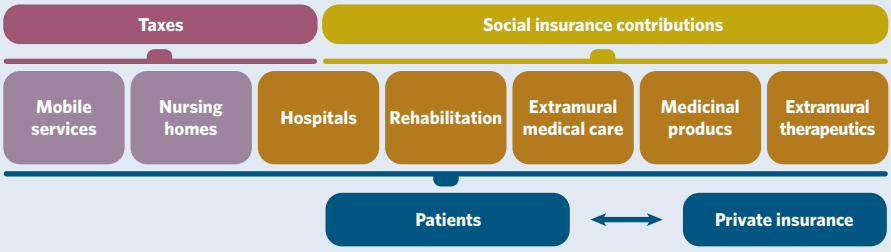
- **Physicians** (general practitioners, group practices, and specialists) **with or without in-house pharmacies**
- **Primary health care units** (PHCU) (currently 64 PHCUs, of which 6 are pediatric PHCUs in 8 federal states) (15)
- **Hospitals and hospital out-patient clinics**
- **Public pharmacies**
- **Other medical/therapeutic services**

Structure of Austria's Healthcare System 2022



Source: Darstellung nach Angaben von Statistik Austria (16), Österr. Ärztekammer (17), Österr. Apothekerkammer (18)

Healthcare financing



Source: BMSGPK (19)

Financial equalization

Financial equalization regulates the financial relations between the federal government, the federal states, and the municipalities. The income from certain levies collected by the federal government is divided between the federal government, the federal states, and the municipalities via the financial equalization system. Financial equalization is an agreement that must be negotiated and adopted by mutual agreement between the federal government, the federal states, and the municipalities. When a financial equalization agreement is concluded, the tasks that each level has to perform and finance are also agreed upon.

At the end of 2023, the federal government, the states, and the social security system agreed on a new five-year financial equalization scheme that will apply from 2024 to 2028. In the area of health, it will provide additional funds, in particular, to strengthen the private practice sector, the hospital outpatient sector, digitalization, and eHealth, as well as health promotion and vaccination (20).

Health target control

The partnership-based target management system for the implementation of the healthcare reform, which has been underway since 2013, pursues the goal of counteracting the strong fragmentation of the healthcare system through joint and cross-sectoral control of the structure, organization, and financing of healthcare. To this end, the system partners on a federal and state governmental level and the social insurance conclude corresponding agreements in accordance with article 15a B-VG on target management for health and on the organization and financing of the healthcare system, as well as contracts based on them (currently valid: 15a-VB 2024–2028). The implementing body is the Federal Health Agency (21,22).

Role model: "Uniform access throughout Austria"

In October 2020, the decision-making body of the Federal Health Agency, the Bundes-Zielsteuerungskommission decided to cover the costs of an innovative therapy approved for the first time by the EU Commission through a **fund established at the federal level. Based on a decision supported by experts, service locations were determined as treatment centers** in Austria that meet the necessary structural criteria for a qualitatively assured implementation of this therapy as well as the associated pre- and post-treatment care (23).

This decision by the Bundes-Zielsteuerungskommission ensures that the Federal Health Agency will cover the costs of newly approved drug therapy for children with spinal muscular atrophy (SMA) under clearly defined indications and conditions and at precisely defined service centers with appropriate expertise in Austria.

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

This means that this cost-intensive therapy is available to all patients insured in Austria, regardless of their place of residence, at all agreed service locations. A major concern of the financiers was also to combine the financing of this novel therapy with demonstrable sustainable treatment success and to scientifically accompany this therapeutic success over several years.

At the end of 2021, the Bundes-Zielsteuerungskommission agreed that another cost-intensive medicinal product therapy (voretigene neparvovec | Luxturna™), which was approved in the EU for the treatment of retinal dystrophies in people with biallelic mutations in the RPE65 gene, was also approved in the EU for the treatment of retinal dystrophies under very clearly defined conditions. If these pioneering pilot projects prove successful, more promising models will certainly follow.

Evaluation Board

At the end of 2023, an amendment to the Hospitals and Sanatoriums Act (KAKuG) adopted a process for the nationwide uniform, systematic evaluation of high-priced specialized medicinal products, the centerpiece of which is the establishment of an evaluation board. Selected medicinal products that are used in hospitals or at the interface between the hospital sector and the private practice sector are affected (24).

Based on Health Technology Assessments (HTA) and the prices negotiated with the companies, the evaluation board shall develop recommendations regarding the use of the evaluated medicinal products and subsequently publish them. When, based on the EU HTA Regulation, a clinical evaluation (Joint Clinical Assessment) is already available at the European level for certain medicinal products, only supplementary assessments may take place at the national level, so that, by law, there are no duplications.

The recommendations relate particularly to the assessment of the additional medical-therapeutic benefit compared to the comparator therapy in conjunction with cost-effectiveness, the application or non-application, certain application criteria or accompanying measures associated with the application (e.g. the establishment and filling of registries) (§ 62e (4) KAKuG).

With regard to the question of what influence the work of the evaluation board will have on the level of treatment and patients' access to innovative therapies, reference should be made to the level of treatment standardized in § 8 (2) KAKuG in accordance with the current state of medical and pharmaceutical science. An evaluation board cannot therefore change the state of science, but is only capable of describing it (25). In addition, it is the responsibility of the treating physicians to determine which treatment methods correspond to the required level of treatment at the state of the art (26).

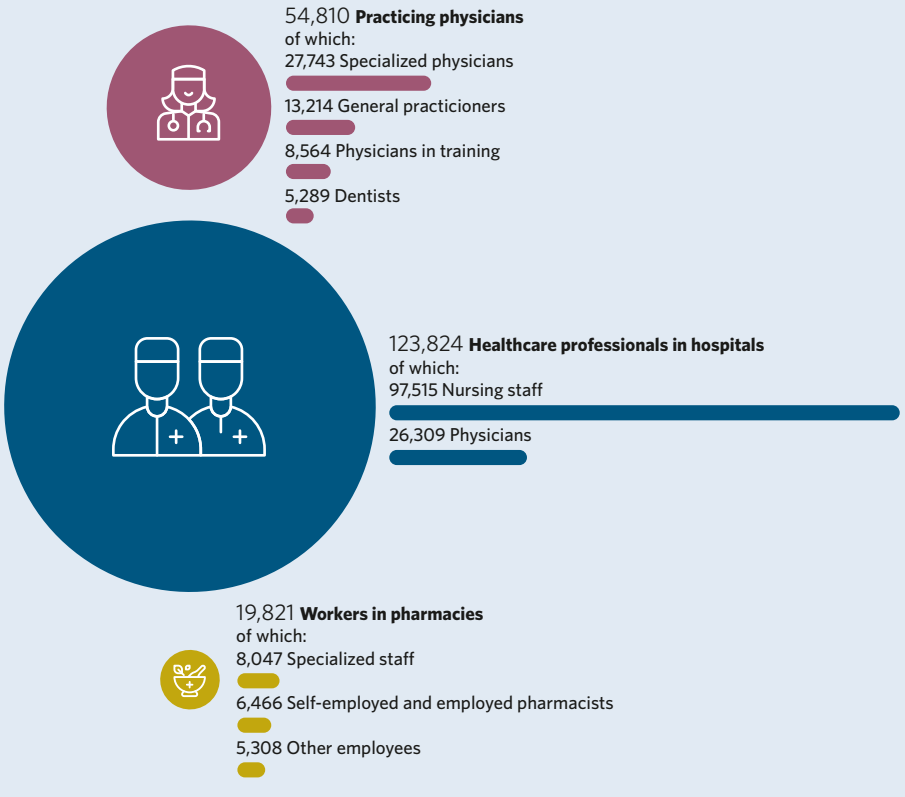
With regard to the legal quality of the recommendations drawn up by the evaluation board, which are to be applied by the hospitals (and hospital operators) through their pharmaceutical commissions (cf. § 19a (3) KAKuG), there could be tension in the light of the above, in that the commissions act without instructions in accordance with § 19a (7) KAKuG (27). Rather, Fuchs and Janko (2023) regard assessments of previous “boards” as recommendations without legally binding character in relation to the decisions of the hospital commissions for this reason alone (28).

It therefore remains to be seen how the work of the evaluation board, which is scheduled to start its work in 2024, will ultimately affect the supply situation in Austria, in particular on patients' access to pharmaceutical innovations.

1.7 Healthcare workers

At the end of 2022, there were 1,415 public pharmacies (with 31 branch pharmacies), 42 hospital pharmacies and 844 self-dispensing doctors in Austria. These provided 9.1 million people with medication (17, 18).

Healthcare Workers 2022



Source: STATISTIK AUSTRIA, Jahrbuch Gesundheitsstatistik 2022 (29), Österreichische Apothekerkammer 30)

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2022: 264 Hospitals

152 acute short-term care

112 non-acute care

6.8 beds

per 1,000 inhabitants = 2nd place internationally

2. Hospitals in Austria

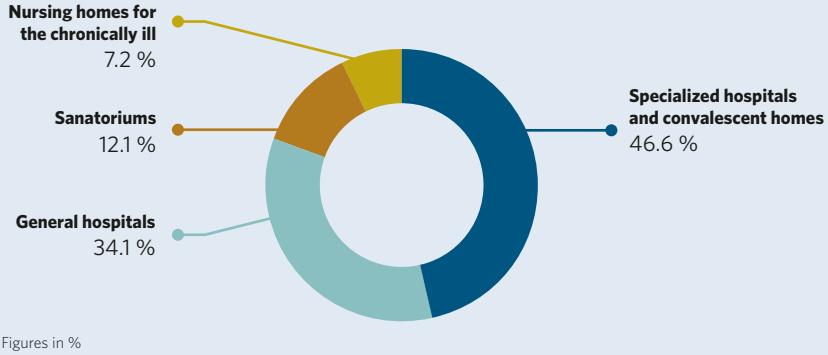
At the end of 2022, there were 264 hospitals in Austria (31). The legal basis for all hospitals is the "Bundesgesetz über Krankenanstalten und Kuranstalten" (KAKuG) (24). This federal law is the basis for the nine state laws, which are the implementing laws. The hospital system is regulated at the level of the federal states.

Hospitals are financed by several sources: mainly from taxes and from lump-sum contributions from the social security institutions to the hospitals, as well as from the states and the federal government. Patients also pay small co-payments (daily benefit) (see Chapter 2.2 Hospital funding).

The following are considered hospitals as per § 2 KAKuG:

- **General hospitals:** for persons without distinction of sex, age, or type of medical care
- **Special hospitals:** for the examination and treatment of persons with certain diseases or of persons of certain ages or for specific purposes
- **Nursing homes for the chronically ill:** requiring medical care and special care
- **Sanatoriums:** Hospitals with special equipment in terms of food and accommodation
- **Independent out-patient clinics:** organizationally independent institutions (e.g. X-ray institutes, dental out-patient clinics) for the examination or treatment of persons who do not require admission to institutional care
- **Military hospitals:** hospitals operated by the Federal Government that are directly and predominantly related to the fulfillment of the tasks of the Federal Armed Forces.

Hospital Types (excluding independent out-patient clinics) 2022



Figures in %

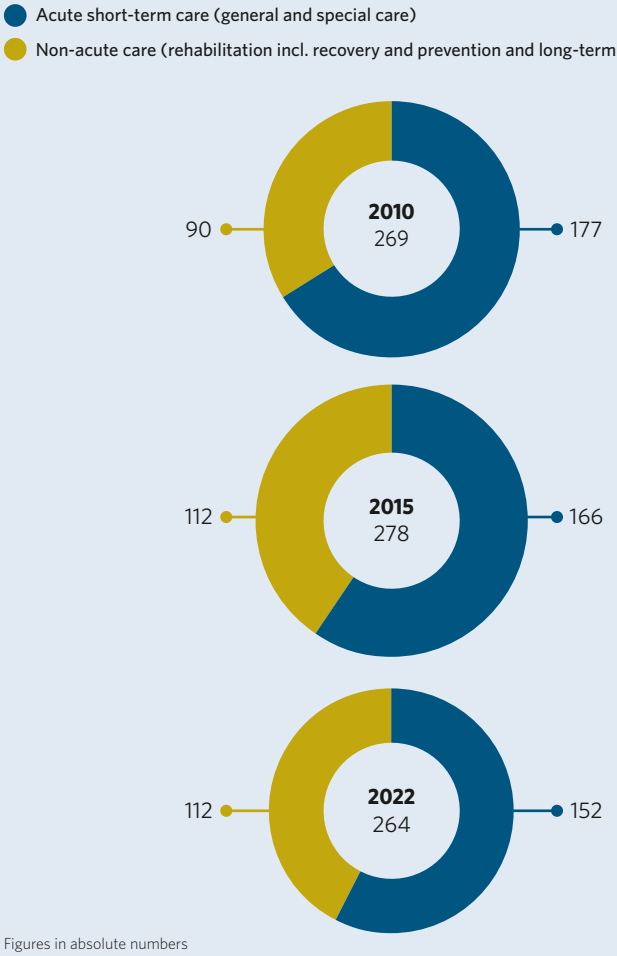
Source: STATISTIK AUSTRIA, Einrichtungen und Personal im Gesundheitswesen (32)

2.1 Structural characteristics of hospitals

Of the 264 hospitals in total, 108 (41 %) have public status and 156 (59 %) do not. Hospitals with public status are not to be equated with hospitals run by public bodies (32).

In 2022, 152 hospitals were available for acute short-term care (general and special care) and 112 for non-acute care (rehabilitation including recovery, prevention and long-term care) (31).

Development of Hospitals According to Care Functions

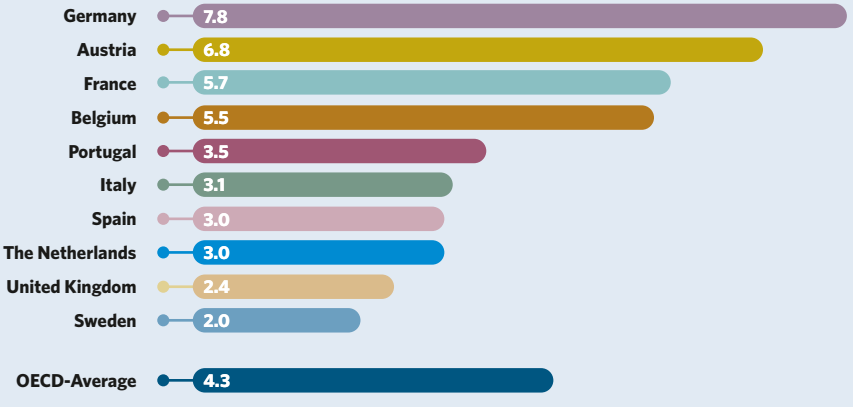


Figures in absolute numbers

Source: BMSGPK - Krankenanstalten in Zahlen (31)

Over the years, the number of acute short-term care facilities has decreased from 177 (2010) to 152 facilities (2022). In comparison, the number of non-acute care facilities has risen from 90 (2010) to 112 (2022).

Number of Hospitals Compared Internationally 2022*



*total, per 1,000 residents, 2022 or most recent data

Source: OECD, BMSGPK (33,34)

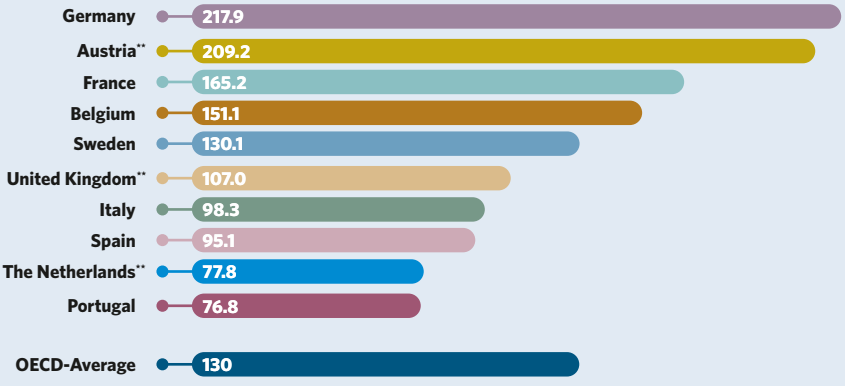
Development of bed availability in Austria

In Austria, a total of 60,739 hospital beds were available in 2022. In relation to the Austrian population, the bed density in 2022 is 6.8 beds per 1,000 residents (compared to 2021: 6.9) (34).

This puts Austria in second place in the OECD country comparison in 2022, behind Germany with 7.8 beds per 1,000 inhabitants, and has 60 % more hospital beds than the OECD country average. Compared to 2008 (7.7 beds per 1,000 inhabitants), Austria is experiencing a slight decline (33).

In line with the high availability of hospital beds, Austria has the second-highest number of hospital treatments per capita in an OECD country comparison at 209, after Germany with 218 (OECD country average: 120) (10,35).

Hospital Discharges Compared Internationally 2022*



Hospital discharges per 1,000 residents
* graphic representation of selected OECD countries with data from 2022 or most recently available
** excluding rehabilitative care, long-term and palliative care

Source: OECD (10.35)

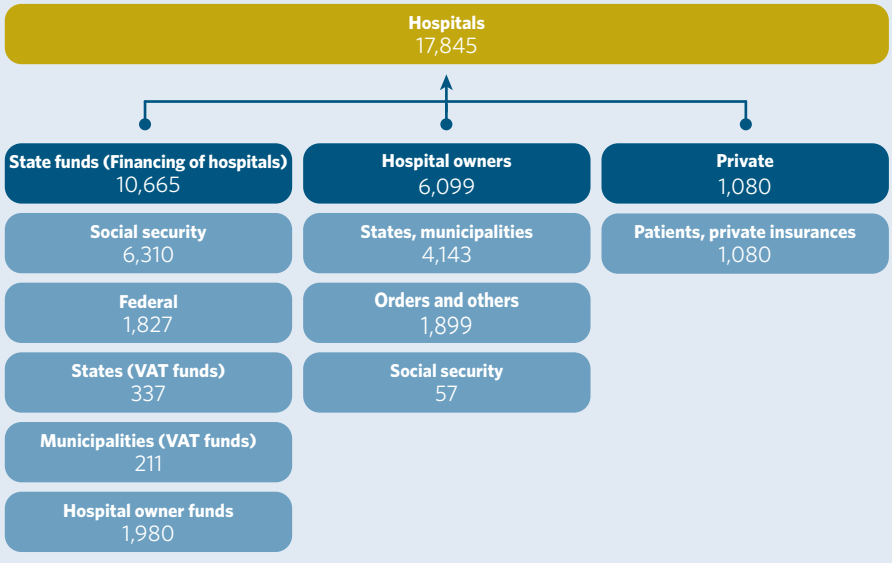
Key figures on hospital discharges in Austria

- **2.2 million in-patient stays were recorded in Austrian hospitals in 2022 (36).**
- **Hospital frequency** (= inpatient stays per 100 inhabitants) **was 25 in 2022** (2010: 33.4 | 2021: 24.8) (37).
- **The average length of stay in acute hospitals in 2022 is 6.2 days** (full-time stays in acute care) (36).

2.2 Hospital funding

The expenditure of Austrian hospitals that bill according to the LKF scheme (performance-oriented hospital financing) amounted to 17.8 billion euros in 2022 (38). More than 60 % of this was financed by state funds. For the remaining costs, the hospital operators had to provide other funds. Patients also contributed directly to the financing, e.g. through private insurance.

Financing of Fund Hospitals 2022



Figures in million euros

* In the Austrian social security system, the institutional care item includes the following expenses: pro rata transfers to the provincial health funds and the Federal Health Agency for inpatient care, payments to other hospitals (Prikraf, accident hospitals, etc.) and payments abroad. Expenses for outpatient services are not included. These are shown under medical assistance and equivalent services (outpatient services in hospitals).

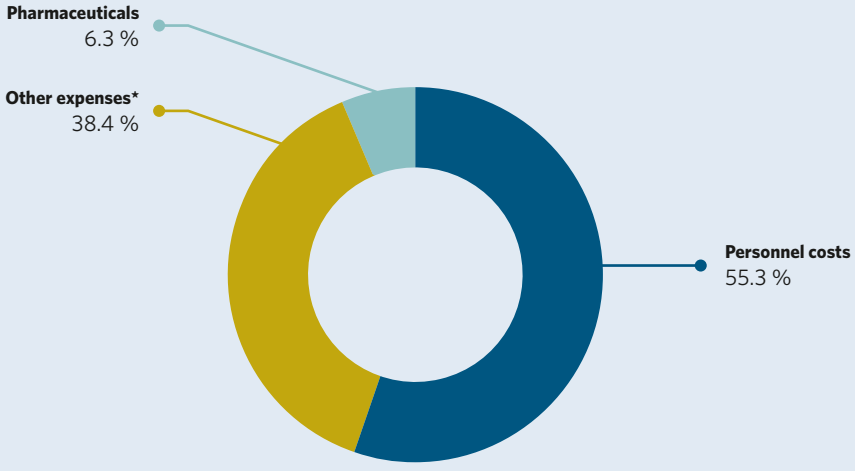
Source: berechnet durch das Institut für pharmaökonomische Forschung unter Verwendung der Daten: Bundesrechnungsabschluss 2022, Krankenanstalten in Zahlen 2022, Statistik Austria SHA. Bundesmittel umfassen: Klinischer Mehraufwand, GSBG, Zweckzuschüsse des Bundes zur Krankenanstalterfinanzierung.

Social security contributes a large part to the financing of hospitals. Of the 10.67 billion euros financed by the state funds, almost 60 % is financed through social security.

State-funded hospitals

The total costs of the hospitals, which are financed by state health funds (109 hospitals with 41,577 beds), amount to 17.8 billion euros. These costs relate to in-patient and out-patient care. More than 50 % of the costs are attributable to human resources, while about 6 % are attributable to medicines and 38 % to other expenses (38).

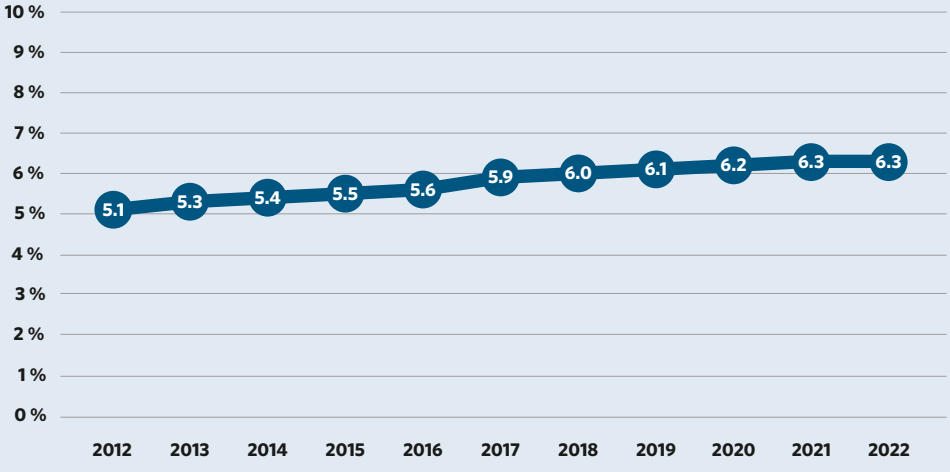
Expenditure in Hospitals 2022



*Catering, training, etc

Source: BMSGPK (38)

Share of medication costs in total costs 2012–2022



Figures in %

Source: BMSGPK - Kosten der landesfondsfinanzierten Krankenanstalten (38)

The share of pharmaceutical costs in total costs in hospitals has only risen slightly in the last 10 years.

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9.1 million People

lived in Austria at the beginning of 2023

from the age of 50

the need for pharmaceuticals increases

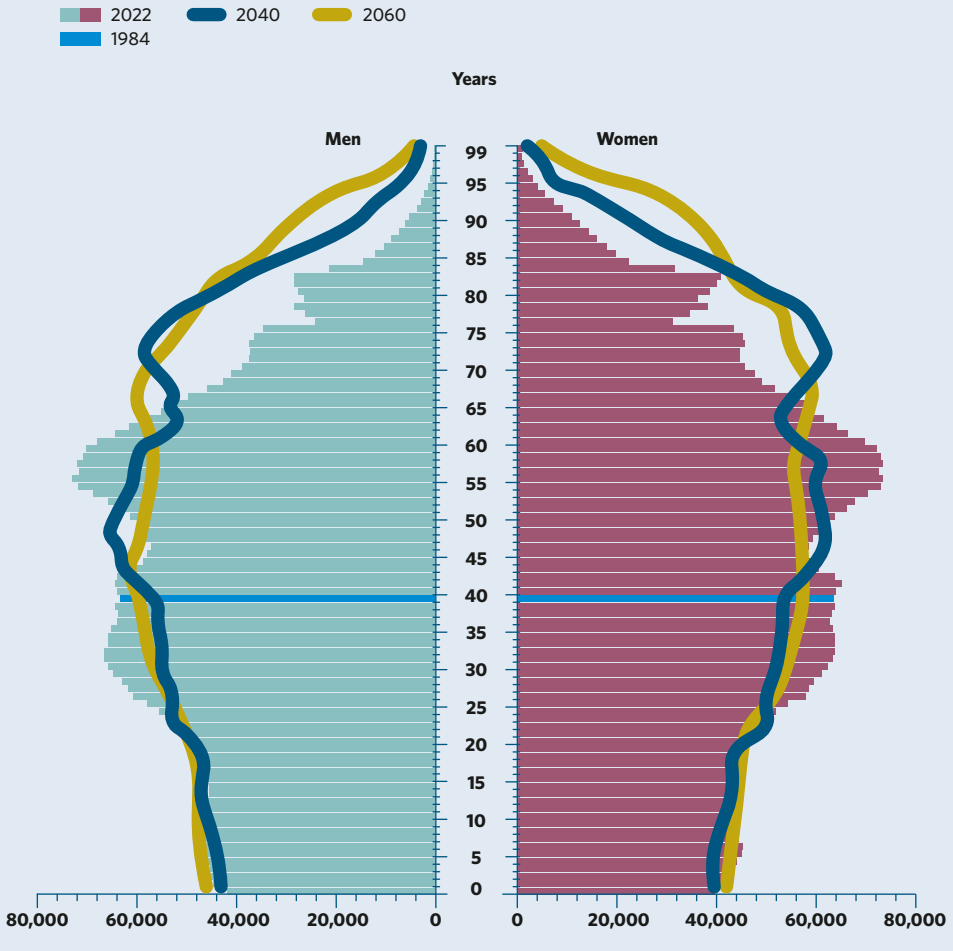
more than 50 percent

of all deaths are caused by cardiovascular disease or cancer

3. Demographic Structure and Demographic Development

3.1 Demographic structure

Population Pyramid 2022, 2040 and 2060



Source: STATISTIK AUSTRIA, Interaktive Bevölkerungspyramide (39)

At the beginning of 2023, 9,104,772 people lived in Austria, according to Statistik Austria. By the end of 2023, a growth of +0.6 % (+55,221) was recorded. For the coming decades, Statistik Austria forecasts a strong population growth, which will be mainly due to migration gains, and a further shift in the age structure towards higher life expectancy (1, 2, 40).

Projected population growth:

- **by 2040:** 6.6 % to 9.7 million people
- **by 2080:** 13.1 % to 10.2 million people

Life expectancy

Life expectancy in Austria has risen continuously over the past decades and is 79.05 years for men (at birth in 2022) and 83.78 years for women. Due to COVID-19, life expectancy has fallen in 2020 and 2021 compared to previous years and has been rising slightly again since 2022 (2).

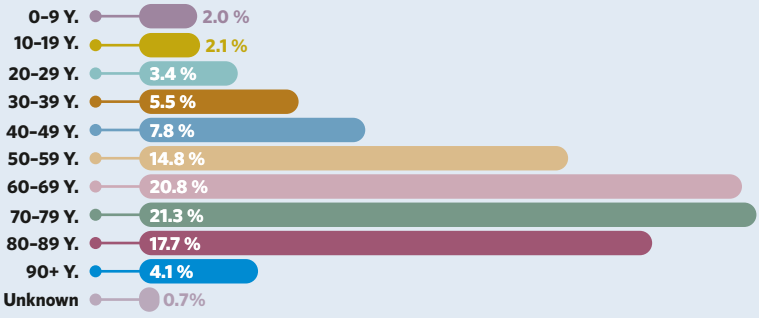
Proportion of age groups in the total population

In 2022, people over 65 made up about 19 % of the total population, while about the same number of children and adolescents under the age of 20 lived in Austria. The number of people of working age aged 20 to under 65 is 61 %. Only just under 1.0 % of the population reached the age of 90 years or above (41).

3.2 Pharmaceutical needs by age group

Pharmaceutical Needs 2023 in %

(Insured patients, by pack)

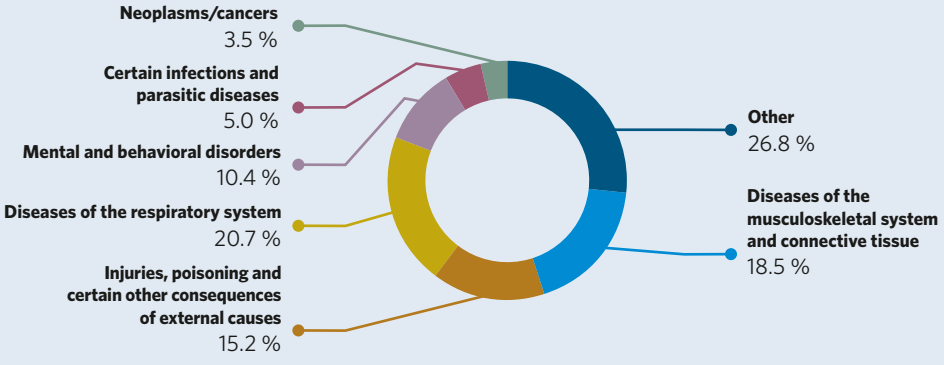


Source: Österreichische Apothekerkammer 2023 (42)

From the age of 50, the need for pharmaceuticals increases sharply.
The pharmaceutical requirement of all persons aged 60 and over is 63.9 % (42).

3.3 Causes of diseases

Disease Groups in 2022 in % of Sick Leave Days



Covered group of people: blue-collar and white-collar workers | Figures in %

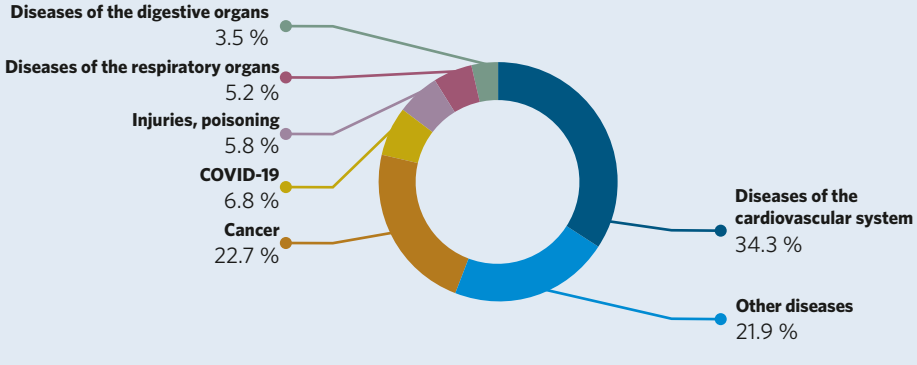
Source: Statistisches Handbuch der österreichischen Sozialversicherung 2023 (14)

In 2022, a total of 5,712,742 cases of sick leave of employed persons were reported, resulting in 53,635,012 sick leave days. **About 39 % of sick leave was due to diseases of the respiratory and musculoskeletal systems.**

The average duration of sick leave in 2022 was 9.4 calendar days (14).

3.4 Mortality

Mortality by Cause of Death 2022



Figures in %

Source: STATISTIK AUSTRIA, Todesursachen (43)

The two leading causes of death – cardiovascular disease and cancer – together account for more than 50 % of deaths. According to reports by Statistik Austria, COVID-19 was the third most common cause of death in 2022 (43).

The death rate has been rising again in the last ten years (2012: 9.4 deaths per 1,000 residents compared to 2022: 10.3). Although almost the same number of men as women died in 2022, the growing number of older people meant that mortality among men was higher than among women, especially for the two most common causes of death (29).

3.26 %

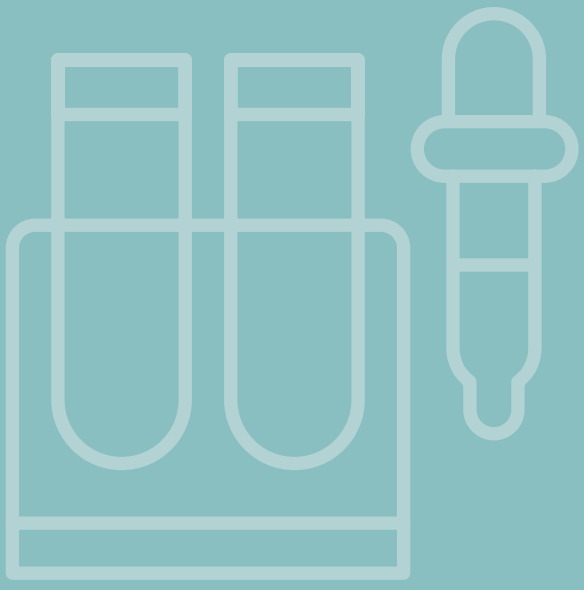
Research quota in 2023

282 clinical trials

have been applied for on average per year
in Austria in the last 5 years.

201 new medicinal products

in the last 5 years in Austria,
36 of them in 2023.



4. Pharmaceutical Research, Development and Manufacturing

Austria as a research location

In the comparative assessment of research and innovation performance of the EU member states for the year 2023, Austria ranks 6th. The "European Innovation Scoreboard", which is published annually by the European Union, once again classifies Austria as a "Strong Innovator". Compared to 2016, Austria has shown a significant improvement of +6.4 %. This puts Austria, together with Ireland, Luxembourg, and other strong innovators (such as Germany, Cyprus, and France), above the EU average in terms of innovation performance. Sweden, Finland, Denmark, the Netherlands, and Belgium are identified as innovation leaders, with innovation performance well above the EU average (44).

The share of expenditure on research and development (R&D) in nominal gross domestic product (GDP) is expressed as the **research quota** as a percentage. This was **3.18 % for 2022 in Austria, above the European target of 3 %.** In the last 10 years, the research quota has risen continuously (2012: 2.91 %).

For 2023, the estimate of the research quota was 3.26 %. In a European comparison from 2022, Austria has the third-highest research rate within the EU behind Belgium (3.43 %) and Sweden (3.40 %).

According to an estimate by Statistik Austria, around 16.6 billion euros will be spent on research and development (R&D) in Austria in 2024 (45, 46):

- **Companies account for** the largest share of total research expenditure **at 51 %** or **8.4 billion euros.**
- **34 %** is covered by the **public sector (5.6 billion euros) and**
- **16 %** from **abroad (2.6 billion euros).**

The pharmaceutical industry in particular contributes to value creation in Austria through research contracts: in 2021, Austrian companies in the pharmaceutical industry invested 304 million euros in research and development (47).

4.1 Active substances

The active pharmaceutical ingredient (API) is the pharmacologically active substance in a medicinal product.

Once a new medicinal product candidate has been identified, it is further developed on a broad scientific basis. To ensure further economic use, the active ingredient is usually patented after its identification. The patented active ingredient then goes through several stages of clinical research. The subsequent classification of active substances is based only on the primary subdivision of investigational medicinal products according to the EudraCT clinical trial submission form without further pharmacological differentiation.

Active substances of chemical origin

Chemical substances are natural chemical substances or products produced by chemical synthesis. Simple chemical medicinal products often have a molar mass of no more than 1000 g/mol. They include medicinal product groups such as antibiotics, cholesterol-lowering medicinal products (e.g. statins), painkillers (e.g. acetylsalicylic acid), or cytostatics.

Generics (see also Chapter 9.5) are copies of original preparations that contain the same active ingredient in the same quantity as the original. They can be placed on the market after the expiry of patent protection and approved in a "pertinent marketing authorization procedure" once the original preparation is no longer protected by patent or data exclusivity. In the case of conventional generics, only simple bioequivalence studies are required to conclude efficacy and safety.

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

Biopharmaceuticals (see also Chapter 9.6) are medicinal products that are produced using biotechnological processes in genetically modified organisms.In contrast to conventional chemical agents, biotechnologically produced active ingredients are complex, high-molecular, and large proteins with molar masses of several thousand g/mol, in some cases even up to 500,000 g/mol. Biopharmaceuticals are classified into different classes, such as immunomodulators, monoclonal antibodies, enzymes, hormones, and vaccines.

Biosimilars are biological medicinal products that are similar to another biological medicinal product ("reference medicinal product") that has already been authorized. To bring a biosimilar to the market, it must be as similar as possible to the reference medicine in terms of quality, safety, and efficacy. Like the reference medicinal product, the biosimilar also exhibits natural, production-related variability. The active ingredient of a biosimilar is essentially the same biological substance as that of the reference product.

Due to the complex structure of the often very large molecules and the individual manufacturing process with special cell lines for each biological medicinal product, biosimilars can only be similar to the original product, but not identical.

Biosimilars are subject to the specific provisions of EU legislation, which include established high standards of quality, safety, and efficacy.

The approval process for biosimilars includes a multi-stage clinical review program that must show that there are no significant differences in efficacy and safety compared to the original product. Typically, biosimilars are approved for the same indications as the reference product after the expiry of the patent protection of the original product.

Biopharmaceuticals offer new therapeutic options for many diseases (including rheumatic diseases, cancer, diabetes, multiple sclerosis, etc.). Their importance in the treatment of many largely life-threatening diseases has steadily increased in recent years. In the European Union, biosimilars have been used in clinical practice since 2006. Depending on market access rules and pricing mechanisms, their market share has grown differently both across EU Member States and across product categories.

4.2 Clinical Research

Clinical research refers to the testing of medicinal products and forms of treatment on humans through clinical studies. The aim is to demonstrate the effectiveness and tolerability of these forms of treatment and to improve medical care for future patients. In principle, a distinction is made between clinical trials (intervention studies) and non-interventional studies.

Legal foundation

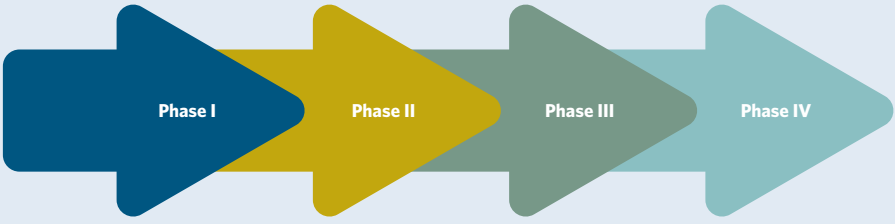
Within the EU, uniform administrative rules for clinical trials have been established since Jan. 31, 2022 in accordance with **EU Regulation 536/2014 on clinical trials with medicinal products for human use.** As of Jan. 31, 2023, new applications for approval can only be submitted in accordance with this new regulation and via the **Clinical Trials Information System (CTIS)** set up for this purpose. Clinical trials that are still running under the old Directive 2001/20/EC have a three-year transitional period. Within this transitional period – until Jan. 31, 2025 – the clinical trials must be completed or converted to the requirements of EU Regulation 536/2014. The national requirements are regulated in the Austrian Medicines Act in §2a and from §28 to §48. An overview of these legal requirements and recommendations is summarized on the BASG website and the platform of the CTR Ethics Committees (48).

Preclinical studies

Before an active ingredient can be tested on humans, its safety must be tested in cell models (in vitro tests) and animal models (in vivo tests). Some tests can be done on cell cultures, but most can only be done on whole organisms. The required animal experiments are required by law and include, in particular, pharmacological, toxicological, toxicokinetic, and pharmacokinetic studies. Preclinical studies are also often carried out in suitable animal models (e.g. knock-out mice) to investigate the efficacy of the active ingredient in vivo. However, meaningful proof of efficacy is not always possible and therefore not mandatory. Only when an active ingredient has passed all preclinical tests can it be used in humans for the first time. This marks the beginning of the development phase of the so-called clinical trials.

Clinical trials

With the help of many volunteers, new medicinal products can be continuously developed to reduce the suffering of patients and give new hope in the case of serious illnesses. By participating in a clinical trial, patients also have the chance to gain early access to innovative, in many cases lifesaving, medicinal products – often years before they are available on the market. However, every clinical trial is also associated with a certain risk. Therefore, all parties involved strive to keep the risks for participants in a clinical trial as low as possible. Clinical trials for the development of new medicinal products are therefore carried out with the greatest care and under strict conditions. An essential prerequisite for any clinical trial is that participation is always voluntary and can be terminated at any time.



Procedure of the individual clinical phases

The relevant information on the marketing authorization of a medicinal product is collected in the clinical trials of phases I to IIIa. Further investigations that are carried out after submission for marketing authorization or after authorization (e.g. long-term studies to influence the course of the disease or detailed studies on pharmacokinetics in patients with renal or hepatic insufficiency) are carried out in so-called phase IIIb or phase IV trials.

Phase I: Testing of pharmacokinetics

In phase I, the active ingredient is used for the first time to determine its behavior in healthy humans (so-called "first-in-man" studies).

Objective: Information on tolerability, absorption, excretion, and possible metabolites. Phase I-testing is carried out on a limited number (about 10 to 50) of healthy volunteers. Healthy subjects are preferred because the pharmacokinetics of the test substance should not be distorted by pathological conditions. However, if it is to be expected that the active ingredient also has toxic properties (such as some substances used in the field of oncological diseases), only patients with the corresponding disease are included in Phase I-testing.

To minimize the risks for study participants, especially in phase I studies, a separate EU directive has been in place since 2007. It stipulates that every Phase I study must be based on an in-depth risk analysis to classify high-risk products accordingly and take the necessary measures. It is also essential that a new substance may not be administered to several test subjects simultaneously, but only one after the other and with a safety interval. Additionally, close, diagnostic monitoring for the individual study participants must be ensured and emergency intensive medical care must be available at all times.

Phase II: Ascertaining the dosage

In the subsequent controlled phase II, the pharmacodynamic effect is investigated.

Objective: Documentation of a biological signal to demonstrate efficacy and to determine the best possible therapeutic dosage. Furthermore, information on tolerability and possible interactions is collected. The patients with a relevant disease to be examined in this phase is between 50 and 200 people. The tests are usually controlled, i.e. carried out with the involvement of a comparison group and double-blind (neither the doctor nor the patient knows whether the active ingredient or the control substance is being administered). This is to avoid a possible influence on the treatment result.

Phase III: Proof of therapeutic efficacy

In contrast to the previous phases, the Phase III trial will be carried out on a large number of patients (with a relevant disease). Depending on the indication area, the size of the patient population is determined to be able to reliably prove efficacy and to record possible rare side effects.

The duration of treatment for individual patients in the clinical trial depends on the disease, and in the case of chronically progressive diseases, can also be several years. As a rule, these multicenter tests are carried out simultaneously in several countries (multinational), mainly to be able to include a large number of patients in an appropriate time frame. The Phase III exams, like those of Phase II, are controlled and conducted in a double-blind manner. If phase III of the clinical trial is successfully completed, an application for approval of the active ingredient can be submitted to the appropriate authority.

Phase IV: Post-approval clinical trials

In this phase, further data will be collected as part of a clinical trial after approval. Phase IV trials are subject to the same legal requirements as Phase I to III clinical trials.

Non-interventional studies (NIS)

With the taking effect of the EU Regulation on Clinical Trials with Medicinal Products for Human Use (Regulation (EU) No. 536/2014) on Jan. 31, 2022, NIS are defined as "clinical studies that are not clinical trials". The NIS is particularly suitable for proving the efficacy of a proprietary medicinal product under practical conditions and for documenting side effects that were not recorded in the clinical trial program due to the limited number of cases. The boundary to clinical trials must not be crossed.

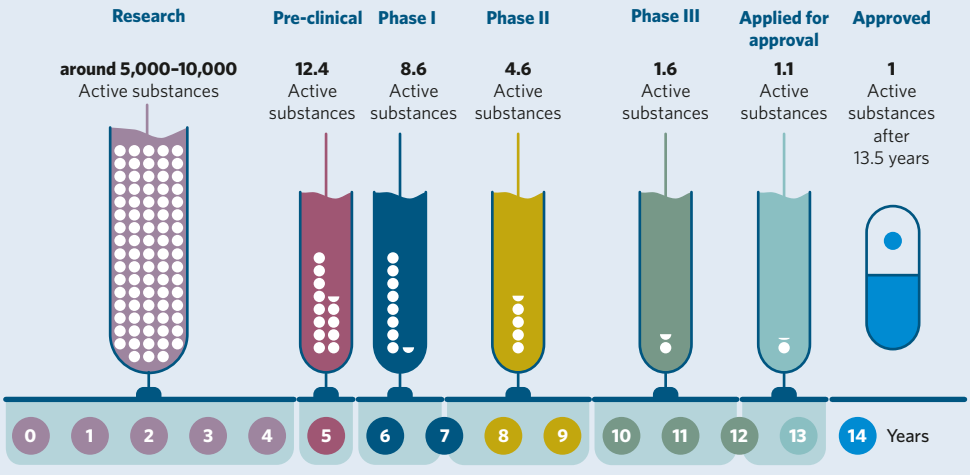
The decision to prescribe the medicine must not be taken at the same time as the decision to include the study participants in the non-intervention study. Furthermore, no diagnostic or monitoring procedures may be used that go beyond normal clinical practice. This is to ensure that the treatment corresponds to the "real world setting", i.e. the usual clinical routine.

In this regard, the BMSGPK and BASG published a guideline in 2022 to differentiate it from other studies, and the "PHARMIG Guideline on the Quality and Transparency of Non-Interventional Studies" has also been updated:

- BMSGPK and BASG Guidelines for the Distinction between Clinical Trial – Non-Interventional Study – Other Study (49)
- PHARMIG Guideline on Quality and Transparency of Non-Interventional Studies (50)

There is no longer an obligation to report NIS. (The previous ordinance on the reporting obligation for NIS was repealed on Oct. 07, 2022.)

Developmental Stages of a Medicinal Product



Source: Paul, S.M. et al.: Nature Reviews Drug Discovery 9, 203–214 (2010) (51)

Development costs

The development of pharmaceuticals is a high-risk process: On average, only one of 5,000 to 10,000 substances is actually approved. According to studies, the average cost of developing a new, innovative drug is up to 2.6 billion US dollars. These costs include the direct costs of developing the drug, the associated failures and the opportunity costs, i.e. the indirect costs of financing these lengthy and cost-intensive development projects. These high costs arise due to the high documentation and safety requirements for clinical trials and the large number of trial participants required. For many substances, it is only in the extremely costly multinational phase III trials that it becomes apparent that they are not sufficiently effective or have side effects that are too burdensome. The costs of the many failed development projects must also be factored in and borne by the companies (52).

Source: EFPIA/PhRMA 2016

Clinical trials in Austria – a statistical overview

The number of initial applications for clinical trials in Austria has increased slightly compared to last year. However, 14 clinical trials are new submissions after previous rejection or withdrawal. This is the highest number of new submissions to date, which was otherwise in the low single-digit range. If these are subtracted, the number of clinical trials in Austria has been stable over the last five years, but at a rather low level.

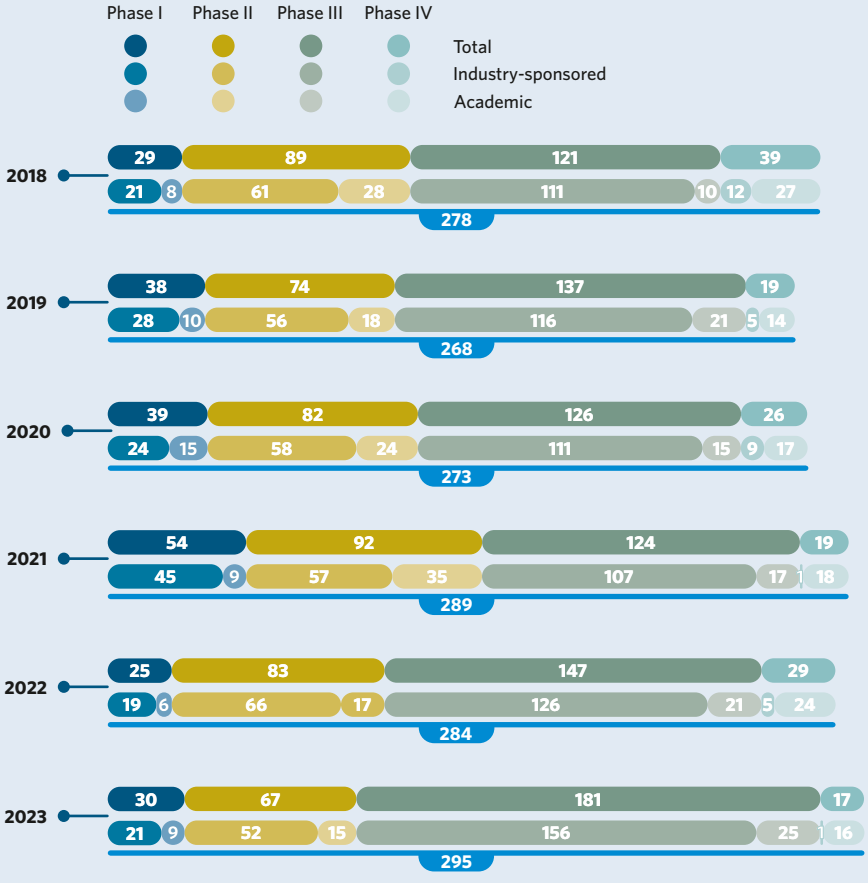
On average in the EU, around 80 % of clinical trials are conducted by the pharmaceutical industry (industry-sponsored) and 20 % by academics (academically sponsored). Austria, with a total share of 22 %, is slightly above this value. However, the share of 22 % is mainly explained by the disproportionately high number of submissions in January 2023, i.e. before the mandatory application of CTR (30 out of 49; 61 %). During the rest of the year, the submissions of academic studies fall behind the submissions of commercial studies according to CTR (35 out of 246; 14 %).

The further alarming decline in academic studies is most likely explained by the fact that commercial and academic studies have been subject to the same fees since 2022. Furthermore, since Jan. 31, 2023, clinical trials can only be submitted in accordance with Regulation (EU) 536/2014 (Clinical Trials Regulation - CTR) and thus in the Clinical Trials Information System (CTIS). Academic sponsors may have made very little use of the new CTIS reporting system due to the formal and technical requirements.

The strong increase in multinational studies can also be explained by the increase in commercial – generally multinational – studies with a simultaneous decrease in academic – mostly national – studies (48). In addition, the CTR is particularly attractive for multinational studies (= one approval for any number of member states).

Austria has taken on the role of reporting member state (RMS) in 39 clinical trials. This puts Austria among the top ten in the EU (48).

Number of Clinical Trials Requested for Medicinal Products by Phase in Austria



Absolute figures

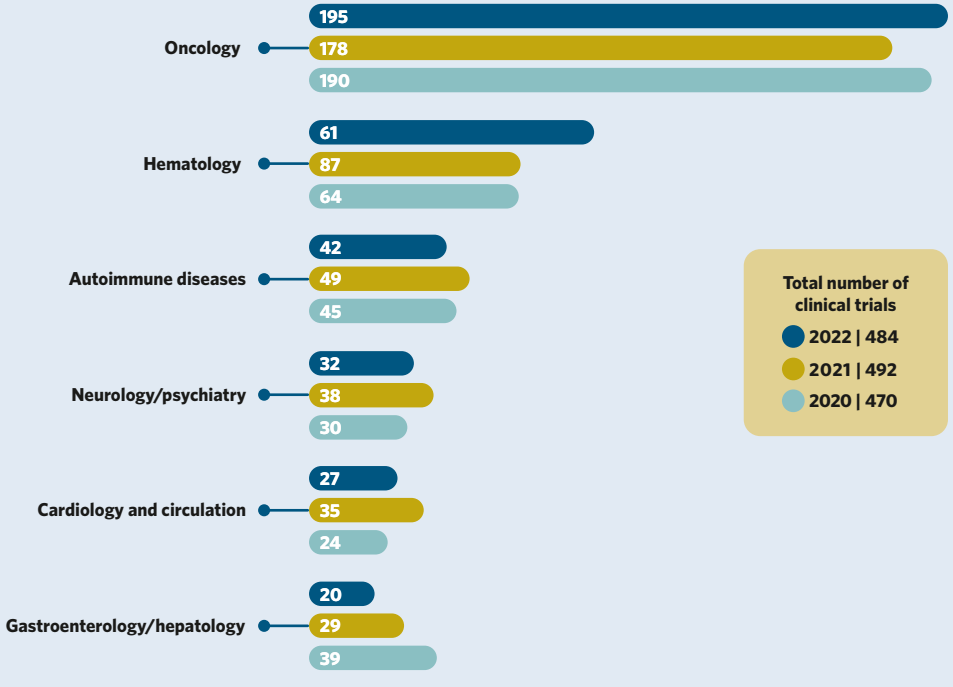
Source: BASG Klinische Prüfungen (48)

Industry-sponsored clinical research in Austria

Once approved, clinical trials often run for several years. An overview of the pharmaceutical industry's performance is therefore best presented in terms of the number of ongoing clinical trials (ongoing, initiated and completed clinical trials) per year according to specified indication areas and the number of patients who have actively participated in them.

To this end, PHARMIG conducts an annual survey of its member companies on industry-sponsored clinical research in Austria. Over the past three years, around 32 companies took part in the survey. This corresponds to a market coverage of approx. 80 % (measured by the turnover of all PHARMIG member companies). In 2022, the survey was revised: the number of non-interventional studies was no longer queried, but instead, the distribution of clinical trials per federal state was surveyed.

Number of Clinical Trials 2020-2022 Broken Down by the most Researched Indications

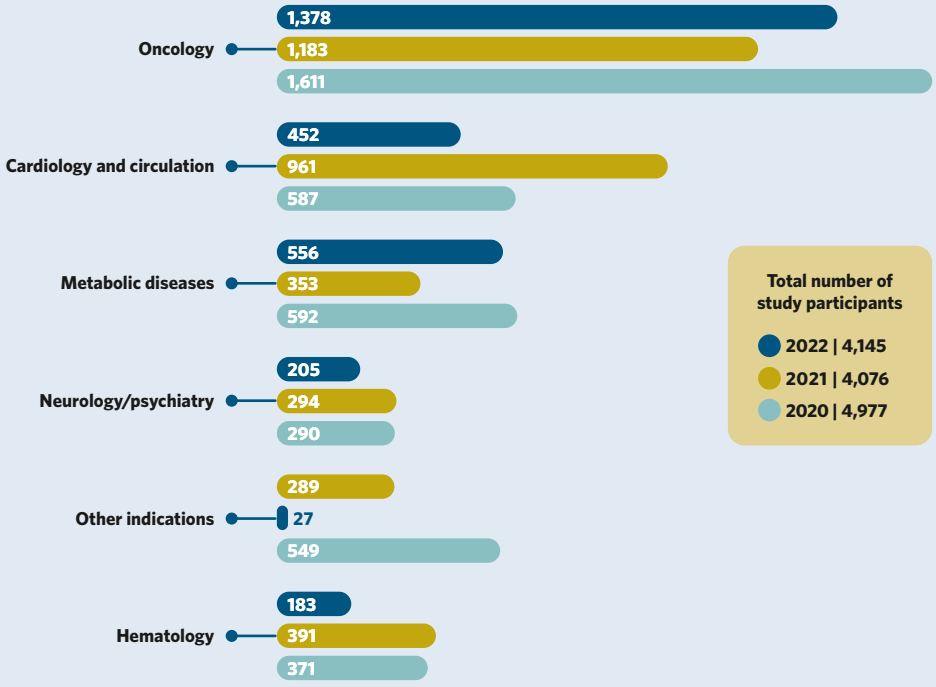


Absolute figures

Source: Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich, PHARMIG 2020-2022

The **average sum** of approx. **482 clinical trials** per year in the years 2020–2022 includes ongoing, started, and completed clinical trials.

Number of Study Participants in Clinical Trials Broken Down by Indication with the Highest Average Number of Participants

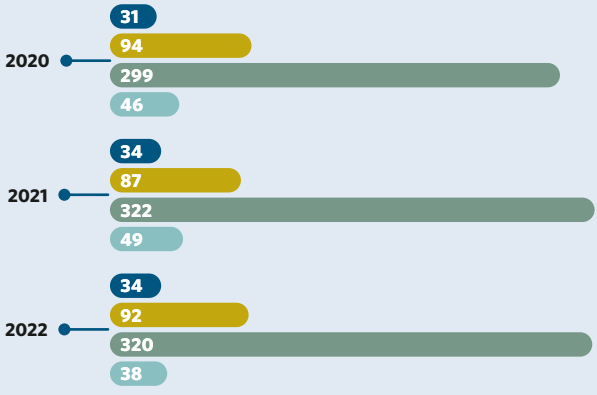


Absolute figures

Source: Umfrage zu Industrie-gesponserter Klinischer Forschung in Österreich, PHARMIG 2020-2022

On average, around 4,399 study participants have taken part in clinical trials in Austria over the past three years. Information on the number of study participants is provided for an average of 80 % of clinical trials.

Number of Ongoing Clinical trials by phase in Austria 2020-2022



Total number of clinical trials

2022 | 484

2021 | 492

2020 | 470

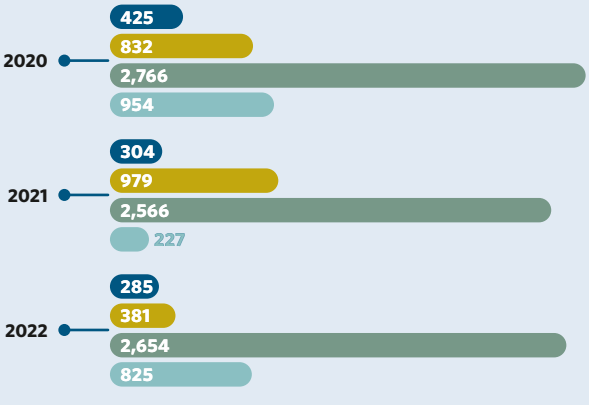
Phase I
Phase II
Phase III
Phase VI

Absolute figuress

Source: Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich, PHARMIG 2020-2022

In addition, the support of the pharmaceutical industry enabled an average of 129 Investigator Initiated Trials, meaning academically funded research projects, per year in 2020–2022.

Distribution of Study Participants in Ongoing Clinical Trials by Phase in Austria 2020-2022



Total Number of Trial Participants

2022 | 4,145

2021 | 4,076

2020 | 4,977

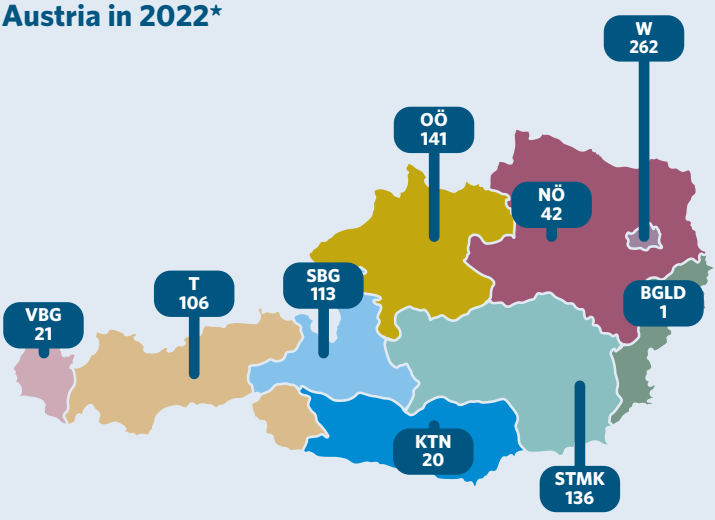
Phase I
Phase II
Phase III
Phase VI

Absolute figures

Source: Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich, PHARMIG 2020-2022

Information on the number of study participants is provided for an average of 80 % of clinical trials.

Distribution of Ongoing Clinical Trials per State in Austria in 2022*



*Data on 74% of the clinical trials. | Absolute figures
Most ongoing clinical trials in Austria are multinational and multicenter, i.e. a clinical trial can run in two or more federal states or centers

Source: Umfrage zu Industrie-gesponserter Klinischer Forschung in Österreich, PHARMIG 2022

	W	NÖ	OÖ	STMK	T	KTN	SBG	VBG	BGLD
Number of inhabitants	1,982,097	1,718,373	1,522,825	1,265,198	771,304	568,984	568,346	406,395	301,250
	22 %	19 %	17 %	14 %	8 %	6 %	6 %	4 %	3 %

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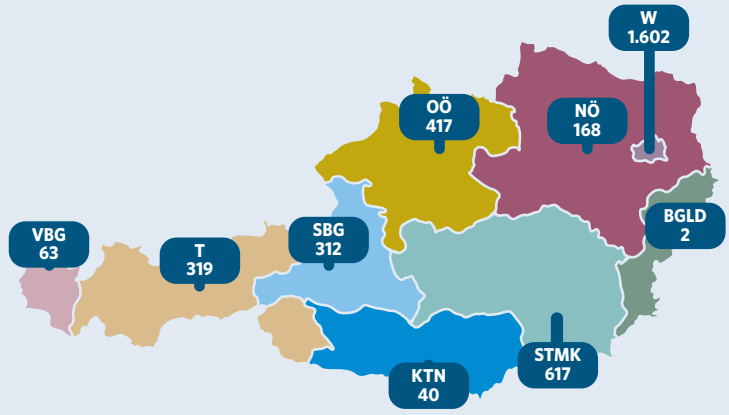
Average Number of Study Participants in Ongoing Clinical Trials per State in Austria in 2022*



*Data for 63 % of the clinical trials. | Absolute figures

Source: Umfrage zu Industrie-gesponserter Klinischer Forschung in Österreich, PHARMIG 2022

Pediatric Pharmaceutical Research

50–90 % of the medicinal products commonly used in pediatrics are not approved for children because children and adolescents have long been excluded from clinical research due to ethnic concerns and legal frameworks. However, an adequate supply of medicinal products that have been tested and approved specifically for children is necessary and has therefore been required by EU regulation since 2007.

A Pediatric Investigation Plan (PIP) must be implemented for all new authorizations, indications, dosages or changes in the method of administration of a medicinal product that has already been authorized. This requires medicinal product studies with children and adolescents (53).

OKIDS – Organization for Pediatric Medicinal Product Research

OKIDS is a public-private partnership that acts as a network for the promotion of pediatric studies in Austria (okids-net.at). It serves as a central point of contact for sponsors of all important stakeholders in pediatric research (pharmaceutical industry, university hospitals, clinical trial coordination centers, specialist departments, etc.). 30 companies started supporting OKIDS in 2013 with basic funding for 5 years together with the Ministry of Health and funds from the "Common Health Goals from the Framework Pharmaceutical Agreement".

After successful admission to the European Children's 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) and c4c (Connect for Children), OKIDS has taken on important tasks in European structural planning and is thus gaining awareness in the European study landscape for pediatric medicines. OKIDS was part of the Enpr-EMA working group on "Trial Preparedness" with a focus on early synergies and collaborations between industry and academic partners in pharmaceutical development.

Transparency of study data

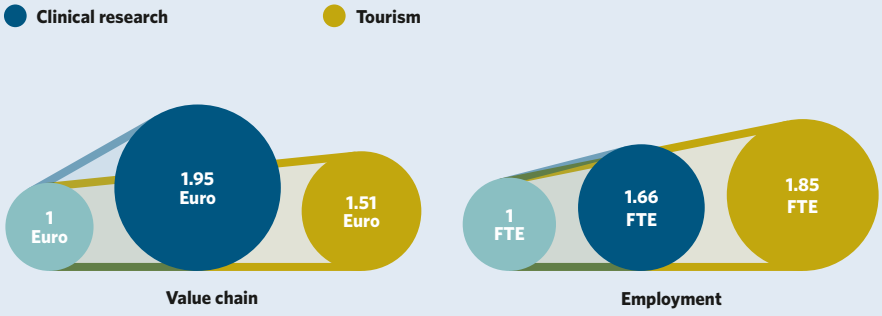
- The **U.S. National Institute of Health (NIH)** has maintained the largest public registry since 2000. It publishes clinical trial data from all 50 U.S. states and another 200 countries: www.clinicaltrials.gov
- Since 2011, clinical trial data from the EU, Iceland, Liechtenstein, and Norway, which have been conducted based on EU Directive 2001/20/EC or will continue to be conducted until Jan. 31, 2025, have been accessible on the European Clinical Trials Register, which is operated by the **European Medicines Agency (EMA):** www.clinicaltrialsregister.eu
- **Information on clinical trials 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) are published on the following website: www.euclinicaltrials.eu

- **A post-authorization safety study (PASS)** is a study carried out after a medicinal product has been authorized to obtain further information about its safety or to measure the effectiveness of risk management measures. These studies are either clinical or non-interventional studies (NIS) and can be ordered by the authorities (54). The EMA publishes the protocols, abstracts, and final reports of PASS studies in the EU Register of Post-Authorization Studies (EU PAS Register): www.encepp.eu
- Based on the **"EMA policy on publication of clinical data for human use",** comprehensive access to clinical trial data from centralized market authorization procedures at the EMA was made available on Jan. 1, 2015 (55). With the first implementation phase, interested parties can access the clinical reports via a registration process on the EMA's website: clinicaldata.ema.europa.eu
- Many companies have voluntarily committed to supporting the responsible use of data from their clinical trials and also provide interested parties with access to comprehensive study data. A summary of the principles of this voluntary commitment can be found under the following link: www.efpia.eu

The Value Creation of Industry-Sponsored Clinical Trials

The added value generated from the conduct of industry-sponsored clinical trials in Austria amounts to 144.2 million euros per year. Each year, a medical treatment value of 100 million euros was funded through 463 industry-sponsored clinical trials with an average value of medical treatment of 37,068 euros per recruited person. The value of this treatment includes the free investigational medication, the assumption of the costs for diagnostics, and therapy as well as administrative services and documentation. This represents a significant share of 0.3 % of current annual health expenditure (56).

Industry-sponsored Clinical Trials



Source: Walter E., Economic impact of industry-sponsored clinical trials of pharmaceutical products in Austria. J Med Econ. 2020 Jun;23(6):566-574 (56).

Every euro invested by the pharmaceutical industry in clinical trials generates 1.95 euros for the Austrian economy. Jobs in the order of 2,021 full-time equivalents (FTE) are created and secured, resulting in an employment multiplier of 1.66 (56).

The overall economic benefit of 144.2 million euros per year is broken down into direct (gross production value), indirect (intermediate consumption relationship of suppliers of clinical trials), and secondary (consumption and investment effect in other economic areas) effects.

Effects	Added value	Employment
Direct effects	74.13 Mio. Euro	1,215 FTEs
Indirect effects	38.47 Mio. Euro	475 FTEs
Secondary effects	31.60 Mio. Euro	331 FTEs
Total effects	**144.19 Mio. Euro**	**2.021 FTEs**
Multiplier	1,95	1,66

Source: Walter E. Economic impact of industry-sponsored clinical trials of pharmaceutical products in Austria. J Med Econ. 2020 Jun;23(6):566-574 (56).

In addition to the benefits for patients, the conduct of clinical trials by the pharmaceutical industry leads to positive macroeconomic effects (contributions to the Austrian healthcare system, but also location and industrial political policies).

4.3 Production and Quality Assurance

Scope of Pharmaceutical Production

Pharmaceutical manufacturing includes the production of medicinal products in their desired form (e.g. tablets, capsules, ointments, injections, etc.), but also the production of the starting materials (active ingredients) and the packaging of the end product as well as quality assurance.

The production of medicinal products is regulated by national, European, and international regulations. Pharmaceutical manufacturers need an official manufacturing license, which requires suitable and sufficient premises, technical facilities and control facilities to be granted. In the European Union, a Qualified Person (QP) must certify for the manufacturer that each batch of a medicinal product has been manufactured and tested in accordance with specifications and regulations.

GMP – The basic rules of production

Pharmaceutical production must be carried out in accordance with Good Manufacturing Practice (GMP), which prescribes proper, hygienic, well-documented and controlled production.

GMP covers the following topics, among others:

- Due diligence obligations
- Training of staff
- Premises
- Separation of production, packaging and storage
- Examination
- Marking
- Hygiene
- Quality of materials
- Rules for self-inspection and third-party inspection
- Supplier Qualification
- In-process controls
- Validation
- Quality control
- Deviation Management
- Change Control
- Complaints and recall

National and international requirements

GMP lays down guidelines for quality assurance of the production processes and environment in the production of medicinal products and active ingredients (57). Quality assurance plays a central role in pharmaceutical manufacturing, as quality control can have a direct impact on the health of patients.

Corresponding guidelines have been approved by the European Commission, the Pharmaceutical Inspection Co-Operation Scheme (PIC/S), the United States Food and Drug Administration (FDA), or the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (58). In Austria, national law is mainly implemented by means of the Medicinal Products Operating Regulations (AMBO (59)).

Monitoring compliance with the applicable regulations is the responsibility of the health authorities of the respective countries. In Austria, this enforcement authority is the BASG and the medical market supervisory authority of the AGES, which is attached to it.

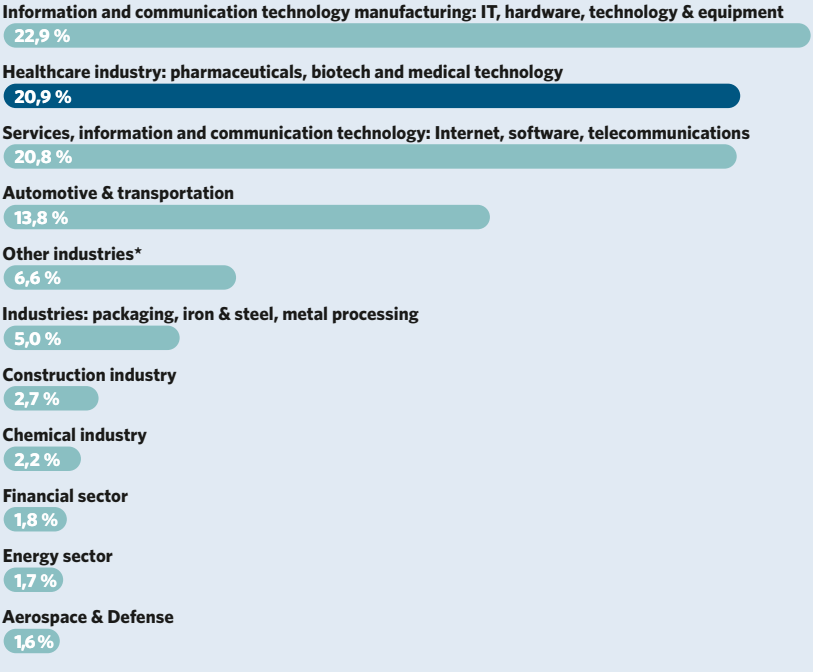
Measures against counterfeit medicinal products

Safety features on each package of medicinal products are intended to make manipulation of the packaging immediately recognizable and to ensure traceability of the medicinal product from the manufacturing company to the pharmacy (see Chapter 6.2).

4.4 Research and Development – Investments

The healthcare industry (biotechnology, healthcare providers, medical technology, and pharmaceuticals) is responsible for about one-fifth of research and development expenditure worldwide.

Research Quota by Sector (Europe)



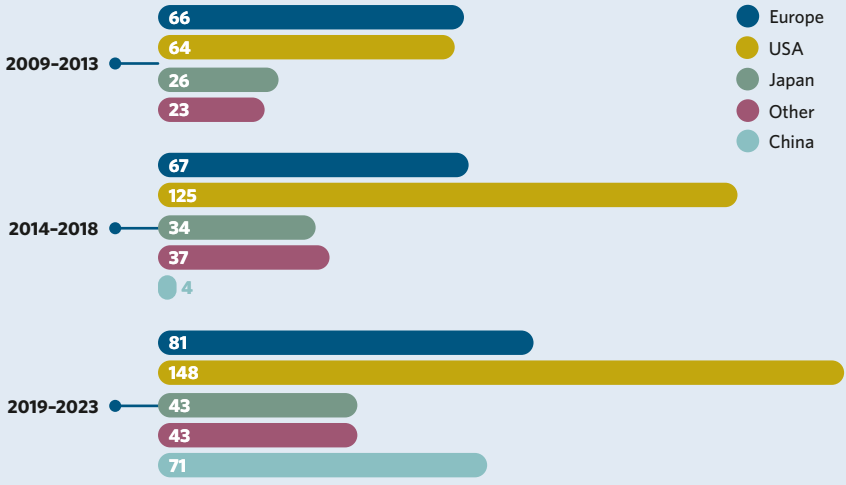
* General Retail; Food Manufacturers; Household Goods & Home Improvement; Media; Travel & Leisure; Personal Goods; Support Services;

Source: The 2023 EU Industrial R&D Investment Scoreboard (60)

In research and development, the "healthcare industry" (pharmaceutical, biotech, and medical technology industry) ranks second behind the information and communication technology sector: 261.4 billion euros were invested in research and development in 2022, which corresponds to approx. 23.4 % of sales (60).

4.5 Pharmaceutical Innovations

New substances by Region



Absolute figures

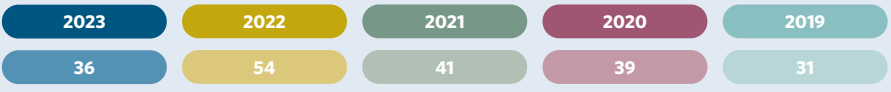
Source: Cleline April 2024 & SCRIP Publications - EFPIA calculations (61)

Innovations 2023 (62):

- **77 new medicinal products for human use** were recommended for approval by the EMA.
- **39 of these contain new active substances** ("New Active Substance").
- The new approvals are for the treatment of cancer, hematological diseases, diseases of the central nervous system, the cardiovascular system, metabolism, etc.
- 2 vaccines against RSV-related respiratory diseases recommended for approval
- First advanced therapy medicinal product (ATMP) with gene editing

In the last five years, a total of **201 medicinal products** with a new active ingredient ("New Active Substance") have been approved in Austria. On average, 40 new treatment options are available per year.

Number of Innovations in Austria



Absolute figures

Source: BASG 2023

Milestones in medicinal product development

Important milestones in medicinal product development since the 1850s are listed here: Milestones in drug development

Year	Event
2020	First Vaccines Against COVID-19, at the same time the fastest developed vaccines of all time with less than a year of development time
2020	First drug against the viral disease hepatitis D
2020	Causally effective drug for cystic fibrosis that has the potential to be used in around 60 % of patients (instead of just a small percentage)
2020/21	First selective immunosuppressive drugs against atopic dermatitis (= neurodermatitis)
2021	First antiviral antibodies against COVID-19; with a development time of less than two years, the fastest developed therapeutic drugs with new active ingredients since the introduction of drug approval
2022	First drug to treat highly accelerated aging caused by Hutchinson-Gilford progeria syndrome or progeroid laminopathy
2022	First gene therapy for people with hemophilia A
2022	First drug against certain genetic forms of obesity
2022	First oral and variant-independent antiviral against SARS-CoV-2
2023	First advanced therapy medicinal product (ATMP) for the treatment of two rare blood diseases using gene editing technology (CRISPR/Cas9)

Source : VFA, Auszug – Meilensteine der Arzneimittelentwicklung
(Alle Angaben beziehen sich auf das Jahr, in dem das Medikament international erstmals auf den Markt kam.)

4.6 Intellectual property rights

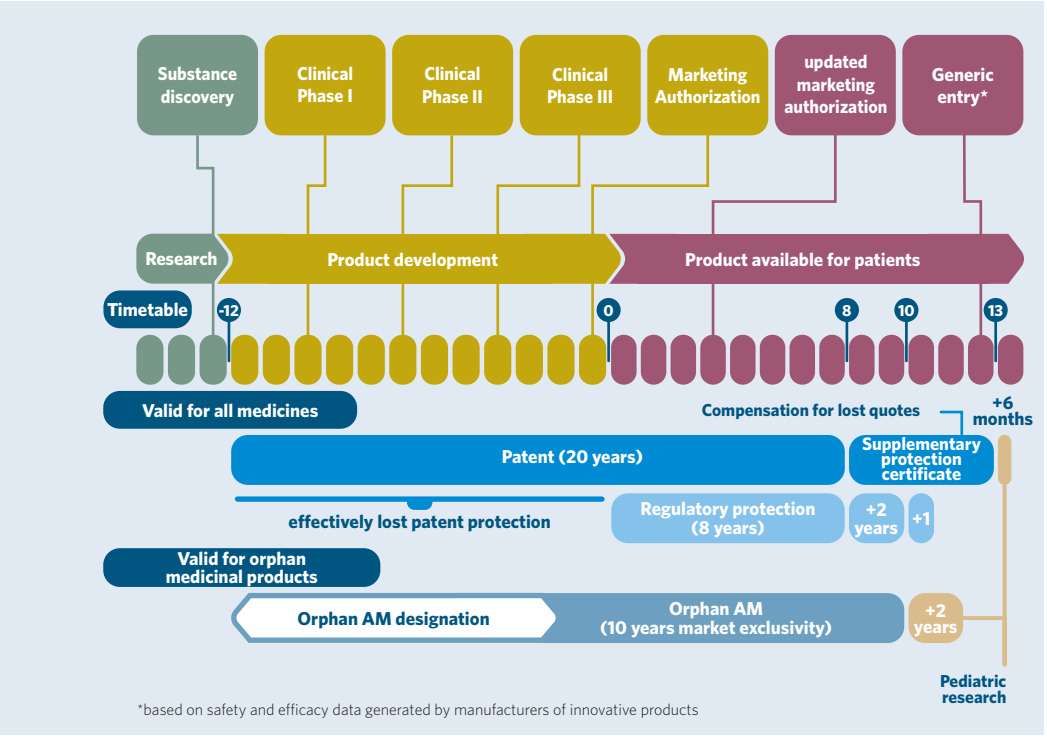
The value of a medicinal product is based not only on its therapeutic performance but also on its research and development performance. As intellectual property, this receives special protection. The term "intellectual property" (IP) includes copyright and related rights, trade secrets and industrial property rights (patents and utility models, trademarks and designs). This protection of intellectual property is the basis for every research-based company to continue investing in research and thus bring innovative products to market.

The protection of intellectual property rights is the best incentive for investment in research and development.

Innovative medicine patents (like all other goods) have a protection duration of 20 years. However, pharmaceuticals must be patented as the intellectual property of the inventors at a very early stage of development. On average, twelve years elapse between patenting and availability to patients, which are needed for preclinical preparation, clinical trials, and approval as a proprietary medicinal product (see Chapter 4.2 and Chapter 5) This results in an actual patent life of only about eight years on average.

The effective patent life is eight years on average.

After the expiry of the last form of intellectual property protection (e.g. patent, RDP, SPC), other companies may manufacture and market medicinal products with the same active ingredient (generics) or with similar active ingredients (biosimilars) (see Chapter 4.1). As a result, original preparations can usually no longer contribute to the refinancing of research and development costs after the expiry of the corresponding IP rights.



*based on safety and efficacy data generated by manufacturers of innovative products

Source: IQVIA, PHARMIG

The table below gives an overview of these and their historical purposes (63):

Type of IP: Patent

Historical purpose:
To encourage private companies to invest in research & development by protecting each invention from imitation for a limited period of time. Owners of the invention can receive a return on investment.

Details:
- 20 years from the filing date
- Publication of the details of the invention 18 months after filing
- Types of inventions: Active ingredients, process, application, improvement, formulation, device
- Criteria for patentability: novelty, non-obviousness, usefulness
- Enforcement by patent holder

Type of IP: Supplementary Protection Certificate (SPC)

Historical purpose:
Extension of exclusivity for a patented medicinal product to compensate for some of the time lost during the lengthy development phase (including clinical trials) and approval phase before a generic or biosimilar can be launched.

Details:
- maximum duration of 5 years
- maximum total exclusivity 15 years from approval (MA)
- only for products with a marketing authorization
- only one SPC per product (i.e. active ingredient or combination of active ingredients)

Type of IP: Regulatory Data Protection (RDP)

Historical purpose:
Protection of medicinal products developers' investments in generating the necessary preclinical and clinical data to obtain marketing authorization against unfair commercial use.

Details:
- 8+2 (+1) years
- 8 years of data exclusivity: generic manufacturers cannot access the preclinical and clinical data
- 2 years market protection: no generic product can be launched on the market
- 1 year additional protection if one or more generics are launched within the first 8 years

Type of IP: Incentives in the field of orphan drugs

Historical purpose:
To ensure that patients with rare diseases (RD) have the same quality of care as all other patients in the EU and to stimulate the development of treatments for rare diseases.

Details:
- 10 years of market exclusivity
- Protocol support, reduced fees for regulatory activities, additional incentives for small and medium-sized enterprises (SMEs)
- New, additional indication or extension of existing RD indication, requires separate assessment by the EMA and approval decision by the European Commission

Type of IP: Incentives in the field of pediatric medicinal products

Historical purpose:
To promote the development and availability of high-quality medicinal products for use in children (pediatric medicinal products). Support the industry by compensating for the additional costs of conducting pediatric research.

Details:
- 6-month extension of the supplementary protection certificate (SPC) after submission of a Pediatric Investigation Plan (PIP)
- If the medicinal product obtains orphan drug status, the 10-year market exclusivity of the EU Regulation on Orphan Medicinal Products (EC) No. 141/2000 can be extended by a further 2 years

Special feature: Roche-Bolar scheme in the EU

The so-called 'Roche-Bolar scheme' enables pharmaceutical manufacturers to carry out studies and investigations on patent-protected medicinal products before the expiry of the patent or supplementary protection certificate to prepare marketing authorization documents (64).

4.7 Use of health data

The **"Austrian Micro Data Center" (AMDC)** has been in operation at Statistik Austria since July 2022. Researchers can use this platform to access anonymized data remotely. Further information on this is publicly available on the AMDC website at www.statistik.at such as the microdata catalog, which contains the available register data, authorized research institutions, technical research institutions, and legal requirements for the application, ongoing projects, etc. (65). Unfortunately, there are currently only a few health data datasets available in the AMDC.

At the European level, creating a European health data space, the so-called **European Health Data Space (EHDS),** is one of the top priorities. Negotiations between the European Commission, the European Parliament, and the Council of the European Union are well underway. The central element of the EHDS is the orientation towards the common good: structured recording, networking and careful use of health data to enable evidence-based decisions for optimized planning, high-quality care, and future-oriented research. In addition to citizens of the European Union, regulators, and political decision-makers would benefit from secure and transparently accessible datasets.

The concept of EHDS distinguishes between primary and secondary use of the data. **Primary use** is intended to provide citizens with better digital access to their personal electronic health data. The control of one's health data and access to it from other EU member states is to be made easier. This plays a decisive role not only for short-term stays abroad but also for commuters and patients who consciously want to use healthcare services in other EU member states.

Healthcare professionals, such as doctors, have the right to access their patients' data electronically, but only to the extent necessary for medical treatment. This data shall include patient summaries, electronic prescriptions, medical images and image reports, and laboratory results. To put this into practice, each EU Member State has to set up access based on the **MyHealth@EU** platform (66).

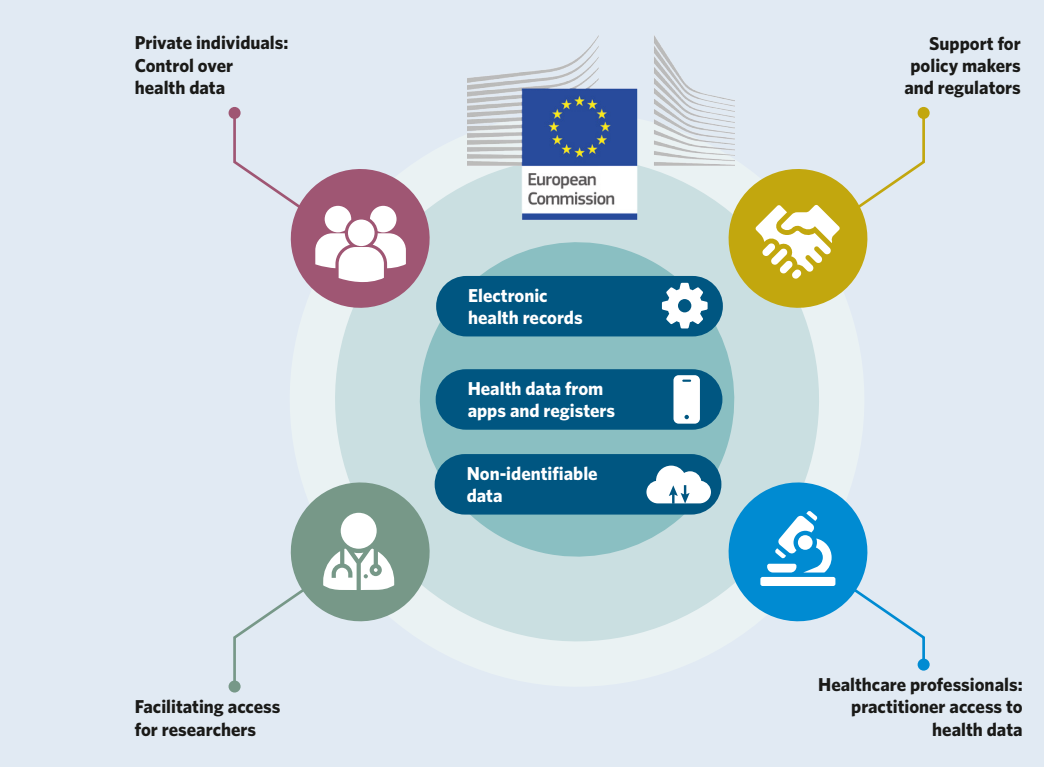
As part of the **secondary use** of the data, scientific research and innovation among other things are to be promoted. The anonymized further use of existing information, i.e. the secure exchange of data for altruistic, non-commercial research purposes, is to be regulated throughout the EU. The interoperability of the data sets in the EHDS plays a decisive role in this. The aim is to facilitate the further development of treatment options and medicines, for example, which will subsequently benefit patients. The aim is to exchange aggregated, anonymized health data – for example information on pathogens, health claims, reimbursements, genetic data, and public health registers – in the public interest. The protection of data takes top priority. The regulation establishing the EHDS is based on various European legal bases*. The disclosure of data for advertising purposes or the evaluation of insurance applications would be prohibited in the regulatory framework of the EHDS (67).

On April 24, 2024, MEPs approved the creation of the European Health Data Space (EHDS). Contrary to the proposed initial text, citizens are to have more extensive co-determination rights. Not only the primary use of personal health data should be restricted. Citizens should also have the right to object to the secondary use of their data in whole or in part (opt-out) or, in special cases, to explicitly consent (opt-in), unless it is research in the public interest.

Now the Council of the EU has to vote on the draft. The result is expected from autumn 2024. The final regulation around the opt-out mechanism will be one of the linchpins in the implementation of the idea of a European space for health data.

Further information and updates on further policy developments:
European Health Data Space (EHDS) (europa.eu) (68)

* General 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 across the Union" (NIS Directive).



Source : Europäische Kommission

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16.112

Authorized medicinal products for human use in Austria (25 % of which are available without a prescription in pharmacies)

72

EU approvals for medicinal products in 2023

5. Medicinal product authorization

Medicinal products may only be placed on the market by the marketing authorization holder if they have been authorized or registered by the authorities. For approval, the applicant must be able to prove that the expected benefit of a medicinal product exceeds the possible risk. Proof is provided by submitting pharmaceutical, preclinical and clinical data.

5.1 Procedures

There are different procedures for the authorization of medicinal products within the EU:

- **National procedure**
  The (purely) national authorization procedure can only be used for a medicinal product that is to be authorized exclusively in one European country. In Austria, the assessment and granting of approval is carried out by the BASG (Federal Office for Safety in Health Care). Legal basis: National Medicines Act of the EU Member State.

- **Mutual recognition procedure (MRP)/decentralized procedure (DCP)**
  These authorization procedures are used when a medicinal product is to be authorized in more than one EU Member State. The principle of the procedures is the mutual recognition of an authorization by the other Member States. The MRP procedure is to be applied if an authorization already exists in a Member State. The DCP procedure is only possible if there is no corresponding approval in this country yet. The applicant is free to choose the Member States in which the medicinal product is to be authorized. The basic prerequisite is the approval of all participating authorities of the EU member states for the application for authorization. Each Member State issues a national marketing authorization at the end of the procedure. Legal basis: Directive: 2001/83/EC

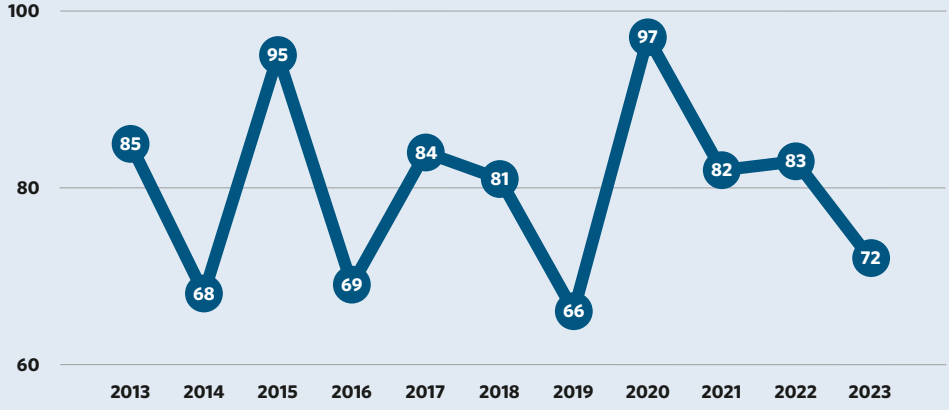
- **Central procedure (EU)**
  Since 1995, there has been a central approval procedure in which European approval is issued at the end. The central approval is carried out by the EU Commission and is valid in all EU member states. Legal basis: Regulation (EC) No. 726/2004

The central authorization procedure is mandatory for biotechnological medicinal products, medicinal products for rare diseases, and medicinal products for human use with **new active ingredients** for therapeutic indications:

- Acquired immunodeficiency syndrome
- Cancer
- Neurodegenerative diseases
- Diabetes
- Autoimmune diseases and other immune deficiencies
- Viral diseases

This procedure is coordinated by the European Medicines Agency (EMA) based in Amsterdam. Two national authorities (rapporteur and co-rapporteur) assess under the supervision of the other national authorities of the member states (Reference Member States). Based on the EMA recommendation, the EU Commission evaluates and grants an EU marketing authorization valid for all member states.

Number of new EU authorizations of medicinal products



Source: Europäische Kommission (März 2023) (69)

5.2 Authorized and registered special medicinal products for human use in Austria

If a medicinal product is authorized under AMG, it is referred to as a proprietary medicinal product. The competent authority in Austria is the BASG (Federal Office for Safety in Health Care) – see organization chart: www.basg.gv.at

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

5.3 Prescription status of new marketing authorizations

(Human medicines incl. homeopathic medicines)

Number of approved proprietary medicinal products for human use 2023	9,223
Chemical medicinal products	8,056
Homeopathic medicinal products	521
Biological medicinal products	383
Herbal medicinal products	160
Radiopharmaceuticals	48
Medical gases	41
Medicinal products that follow/correspond to an ÖAB/Ph. Eur* monograph	14

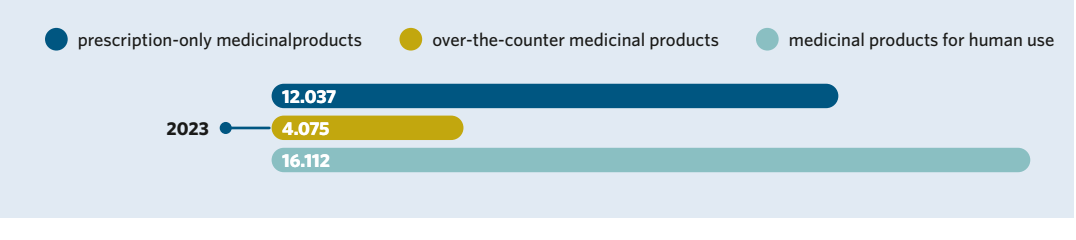
Source: BASG-Statistiken 2023 (70)

Number of registered human medicinal specialties 2023	3,018
Homeopathic remedies	2,022
Pharmacies' own medicines	636
Traditional herbal registrations	207
Allergen manufacturing processes	153

Source: BASG-Statistiken 2023 (70)

*Section 9c of the Medicines Act

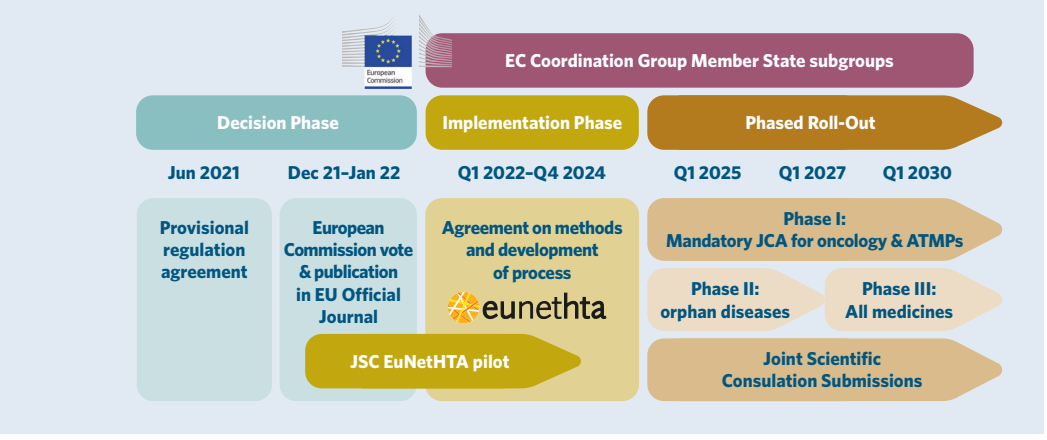
As part of the authorization procedure, the prescription status of a medicinal product is also determined. The legal basis is the Prescription Obligation Act and the Prescription Obligation Ordinance. **Around 25 % of the medicinal products for human use approved in Austria are available without a prescription in pharmacies.**



Source: BASG-Arzneispezialitätenregister (Stand 28.03.2024) (71)

5.4 Health Technology Assessment (HTA)

Health Technology Assessment (HTA) is the **systematic evaluation of medical procedures and technologies** (a large part of which relates to pharmaceuticals and medical devices) in healthcare. For this purpose, all available data is presented and evaluated under a specific question. HTA reports are often the basis for decisions by physicians, health authorities, health insurance providers, and other payers on the medical and health economic value, as well as the social and ethical framework of the respective issue. The European Commission's "Regulation on the Assessment of Health Technologies" (Regulation (EU) 2021/2282) entered into force in January 2022 and will apply from January 2025 (72). It regulates how health technology assessments are to be carried out at European level in the future. The assessment at European level is limited to a comparison with treatment options already used in terms of clinical dimensions. How the findings of the joint clinical assessments are dealt with remains a matter for the individual EU member states. The implementation and roll-out phase is set to run until 2030 (73).



Source: Europäische Kommission, EFPIA

The Regulation aims to:

- Use **resources** efficiently and improve **HTA quality standards across the EU**
- **Avoid duplication** of the work of national **HTA bodies** and industry
- Provide **companies with safety** and
- ensure the long-term **sustainability** of **HTA cooperation in the EU**
- and thus provide **patients** with better, faster access to **innovative medicines and medical devices in the EU.**

The management of health services, including pricing and reimbursement of medicines, remains the responsibility of the Member States.

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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 includes the teaching and all activities related to the detection, evaluation, understanding, and prevention of adverse reactions and other problems that may arise in connection with medicines, such as improper use, abuse, and quality defects.

The objectives of pharmacovigilance are:

- The prevention of harm from side effects from the use of medicines within and outside the scope of their regulatory approval, or from occupational exposure.
- Promoting the safe and effective use of medicinal products, by informing patients, and the public about the safety of medicines in a timely manner.

Pharmacovigilance contributes to the protection of patients and public health.

Pharmacovigilance system

The pharmacovigilance system serves the marketing authorization holders and the competent authorities of the EU Member States to fulfill their tasks and responsibilities under Title IX of Directive 2001/83/EC. It monitors the safety of medicinal products and detects any changes in their benefit-risk ratio, i.e. the assessment of the positive therapeutic effect of the medicinal product in relation to the risks in terms of quality, safety, and efficacy.

Good Pharmacovigilance Practices (GVP) is a set of measures designed to facilitate the implementation of pharmacovigilance in the European Union.The GVP modules I to XVI cover the most important pharmacovigilance processes (74).

6.1. Post-authorization pharmacovigilance

The European Commission and the national authorities decide on the authorization of medicinal products after assessing the results of preclinical and clinical trials. Only medicinal products whose benefits demonstrably outweigh the risks are placed on the market. This ensures that patients have access to the treatments they need without being exposed to unacceptable side effects. As a rule, only a limited number of patients take part in clinical trials for a fixed period of time under controlled conditions.

Under real conditions, a larger and more heterogeneous group of patients will use the product. They may suffer from various diseases and take other medicines.

Some less common side effects and interactions may not occur until a medicinal product is used by a large number of people over a long period of time and, if necessary, in combination with other products. It is therefore essential that all medicinal products continue to be monitored for safety as long as they are on the market.

The Black Triangle

The European Union has introduced labeling for medicinal products that are monitored particularly closely. These medicinal products are identified by an inverted black triangle in the package leaflet, together with the following short sentence: ▼ **"This medicinal product is subject to additional monitoring."**

All medicines are carefully monitored after they are placed on the EU market. In the case of medicinal products marked with the black triangle, this monitoring is even more closely meshed. This is the case when there is less information available than for other medicines:

- Medicinal products containing a new active ingredient that was authorized in the EU after Jan. 1, 2011.
- Biological medicinal products (e.g. vaccines, plasma-derived medicinal products) authorized in the EU after Jan. 1, 2011.
- Medicinal products with a conditional marketing authorization or a marketing authorization in exceptional circumstances.
- Medicinal products for which further studies are required (e.g. data on long-term use or rare adverse reactions observed during clinical trials).

Additional monitoring may also be required for medicinal products that have already been authorized if recommended by the Pharmacovigilance Risk Assessment Committee (PRAC) (75).

However, the black triangle does not mean that the medicinal product is unsafe.

Side Effect Reporting and Evaluation

Manufacturers and medicinal product authorities systematically search for further, still unknown side effects after approval. The most important source of information for this is spontaneous reports: healthcare professionals such as doctors and pharmacists are legally obliged to report suspected cases of side effects that have occurred in patients they care for. Since 2012, patients have also been able to voluntarily report side effects. There is an online reporting form for this on the BASG website: nebenwirkung.basg.gv.at

The BASG records all suspected side effects of medicinal products and vaccines that have occurred in Austria. Once processed and reviewed, the data will be forwarded to the EMA in accordance with applicable European regulations. This means that the data is available to all national medical authorities for ongoing safety monitoring.

Marketing authorization holders of medicinal products submit all suspected adverse reactions that have occurred in Austria, as well as side effects from use observations and case reports from the literature, directly to the EMA's EVPM (Eudravigilance post-authorization module).

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

Costs of pharmacovigilance

In order to fulfill legal obligations for medicinal product monitoring, the industry has to make considerable expenses. These include, among other things, the installation of its pharmaceutical monitoring systems, the reporting of suspected cases of adverse reactions, literature research, signal detection, and the preparation of regular reports to demonstrate medicinal product safety (PSURs). In addition, the ongoing technical connection and provision of information to official databases must be guaranteed.

With the amendment of the European pharmacovigilance laws in 2012, there was an increasing shift of regulatory tasks in the field of medicinal product monitoring from the Member States to the European Medicines Agency (EMA). This was accompanied by a considerable increase in fees. In addition to an annual fee for the maintenance of the EMA's IT systems, there are additional procedural fees in the five- to six-digit range for PSURs, post-authorization safety studies, and pharmacovigilance-related assessment procedures. It is estimated that an average pharmaceutical company with a wide range of active ingredients spends up to 20 million euros per year in pharmacovigilance fees alone (76).

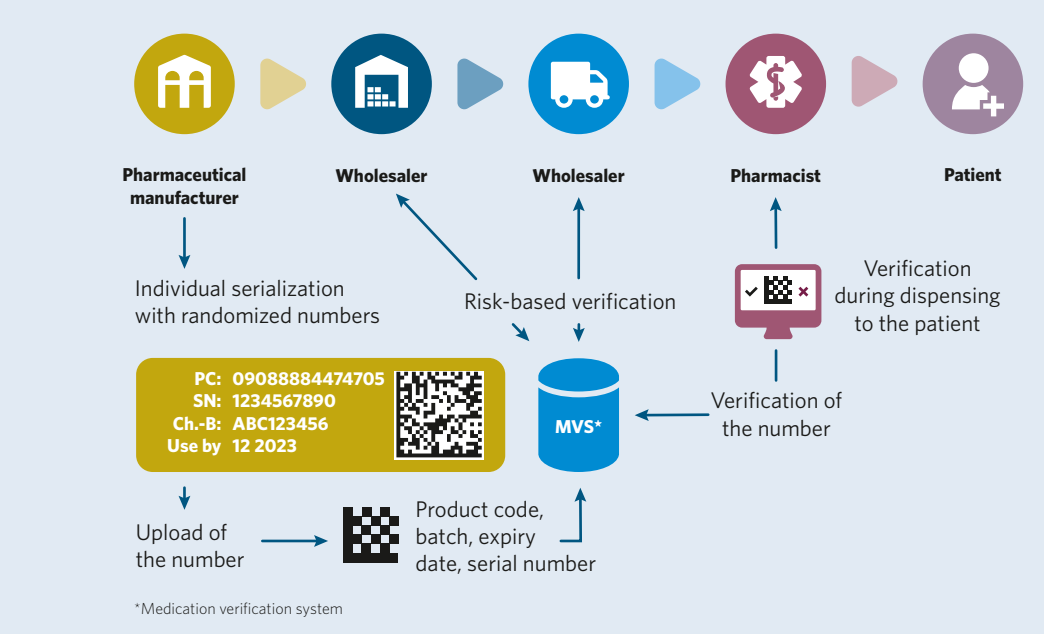
6.2. Measures to protect against counterfeiting

The detailed legal requirements for the traceability of medicinal product packages are laid down at the EU level by Delegated Regulation (EU) 2016/161. These regulations have been applicable since Feb. 09, 2019.

Delegated Regulation (EU) 2016/161 requires two safety features on the packaging of prescription medicines for human use:

- A unique identifier that makes each package uniquely identifiable via the product code it contains.
- An anti-tampering device that detects whether the outer packaging of a medicinal product is intact.

Coding and Serialization of Medicinal Products

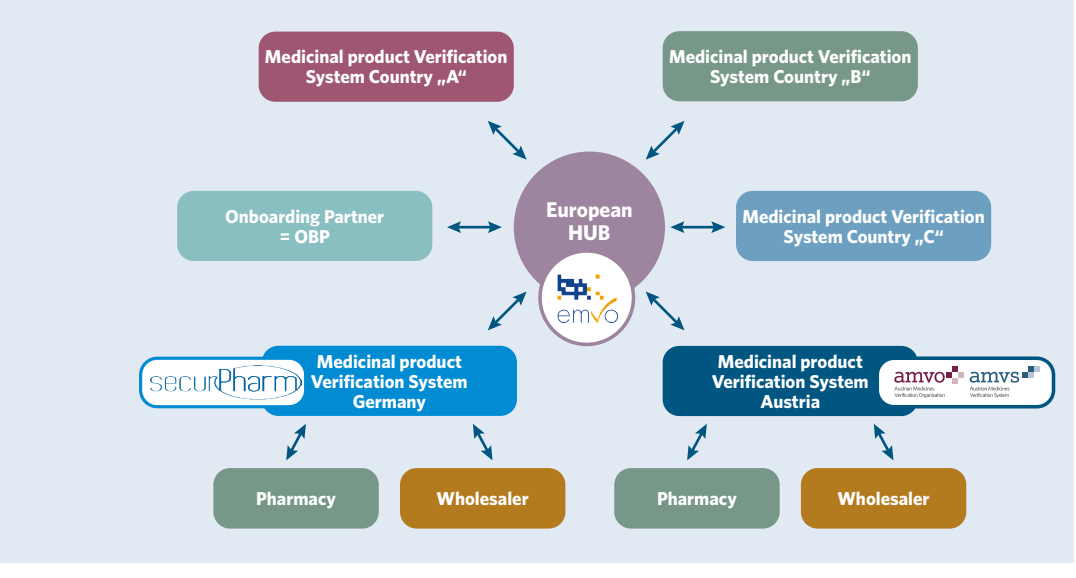


Source: EFPIA

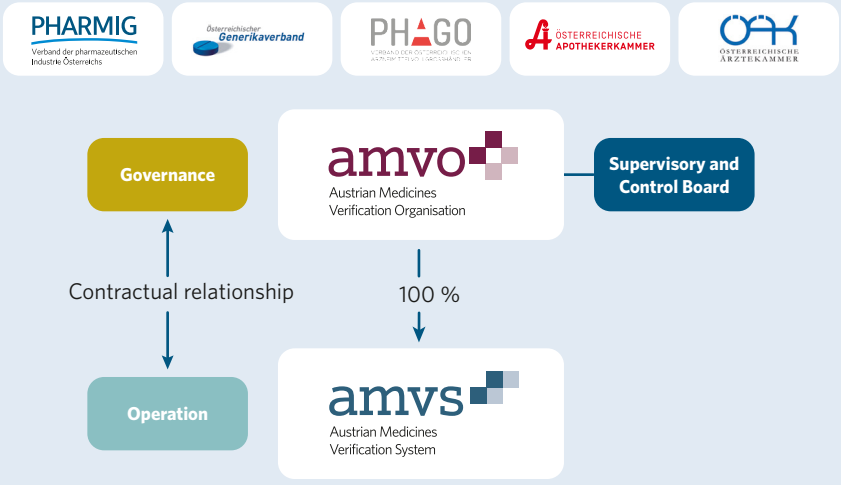
In principle, all prescription medicinal products for human use are affected. Exceptions are listed in Annexes 1 and 2 of the Delegated Regulation. Each package must be provided with a randomized, unique serial number, which is encrypted into a two-dimensional barcode (GS 1 Data Matrix) together with the batch number and expiry date. This is affixed to the packaging by the pharmaceutical industry and stored in a database. While wholesalers only have to check the code in defined cases (e.g. when buying from another wholesaler or in the case of returned goods), the mandatory verification and deactivation of the serial number takes place directly when it is dispensed to patients (mainly in pharmacies). A deactivated serial number means that the pack has already been dispensed. If the same serial number appears again at a later date, there is a suspicion of forgery.

The European System for Medicinal Product Serialization

For this process, a data storage and retrieval system was set up by the pharmaceutical manufacturers and marketing authorization holders with the involvement of other stakeholders (e.g. wholesalers, parallel distributors, and pharmacists) in accordance with the Delegated Regulation. The authorities control and supervise. The EMVO (European Medicines Verification Organisation) operates the so-called "European Hub", into which all pharmaceutical data from the industry must be imported. Then, these are divided among the respective national systems. 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 respective 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.
For example, packs that can be dispensed in several countries (so-called "multimarket packs") can also be deactivated in all national systems.



Source: EFPIA



Source: PHARMIG

Implementation in Austria

In Austria, the AMVO (Austrian Medicines Verification Organization) is responsible for the governance of the medicinal product verification system. The AMVO is also the publisher of the coding rules for Austria.

Members of the AMVO are PHARMIG, the Austrian Generics Association, PHAGO (Association of Austrian Pharmaceutical Wholesalers), the Austrian Chamber of Pharmacists, and the Austrian Medical Association. The Supervisory and Control Advisory Board involves the competent authorities so that they can carry out their sovereign monitoring tasks.

AMVO founded AMVS GmbH (Austrian Medicines Verification System GmbH) for the technical operation of the Austrian data storage and retrieval system "AMVSystem". All affected stakeholders are connected to the system operated by AMVS GmbH in order to comply with their legal obligations.

Further information can be found at:
www.amvs-medicines.at or www.amvo-medicines.at

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1.23 years

Life expectancy increase in the period
from 2006 to 2016

approx. 500,000

People in Austria suffer
from rare diseases

4,393 applications

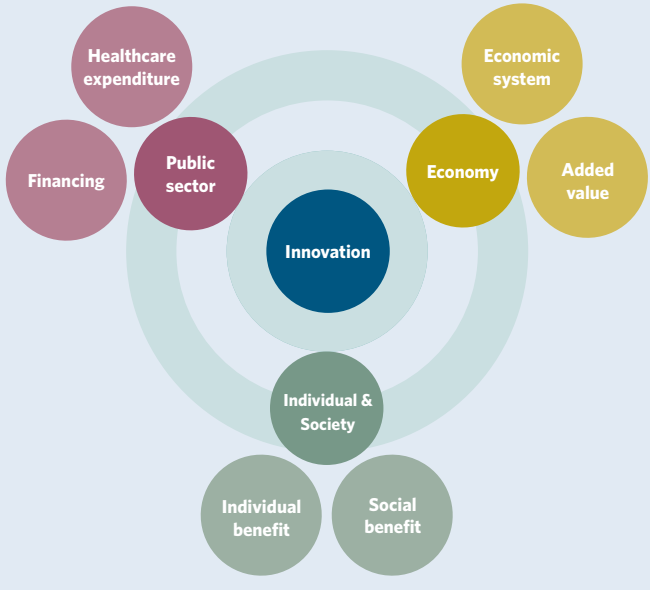
in the period 2000 to 2023 with
244 approved orphan drugs (ODs)

7. Benefits of Innovative Therapies

Medicinal products make an important contribution to our society: they help to cure, alleviate, or prevent diseases. Based on new scientific findings – about fundamental biological processes or specific diseases – novel medicinal products are being developed that can be used to treat patients better or for the first time. Medicinal products and medical progress make a significant contribution to a longer life. An analysis of data from the US and 26 other high-income countries shows the link between pharmaceutical innovation and life expectancy: between 2006 and 2016, life expectancy increased by 1.23 years, with 75 % of this improvement attributable to pharmaceutical innovation (77).

Where and how innovative medicinal products therapies work – on the individual and society, on the public sector and the economy – is shown by a study by the IHS from 2021 (78). In addition to medicinal products, innovations in healthcare also include diagnostic or therapeutic procedures whose effects go beyond the direct benefit for patients (extended life expectancy and improved quality of life). Social effects can be seen, for example, in shortened or avoided hospital stays and reduced care costs for relatives. Innovations are relevant in various areas of healthcare; in prevention, they generate benefits for society as a whole, as cases of illness can be avoided. The burden of disease decreases both for those affected and for society if an illness is completely absent.

Conceptual presentation
Impact of innovation in the healthcare sector



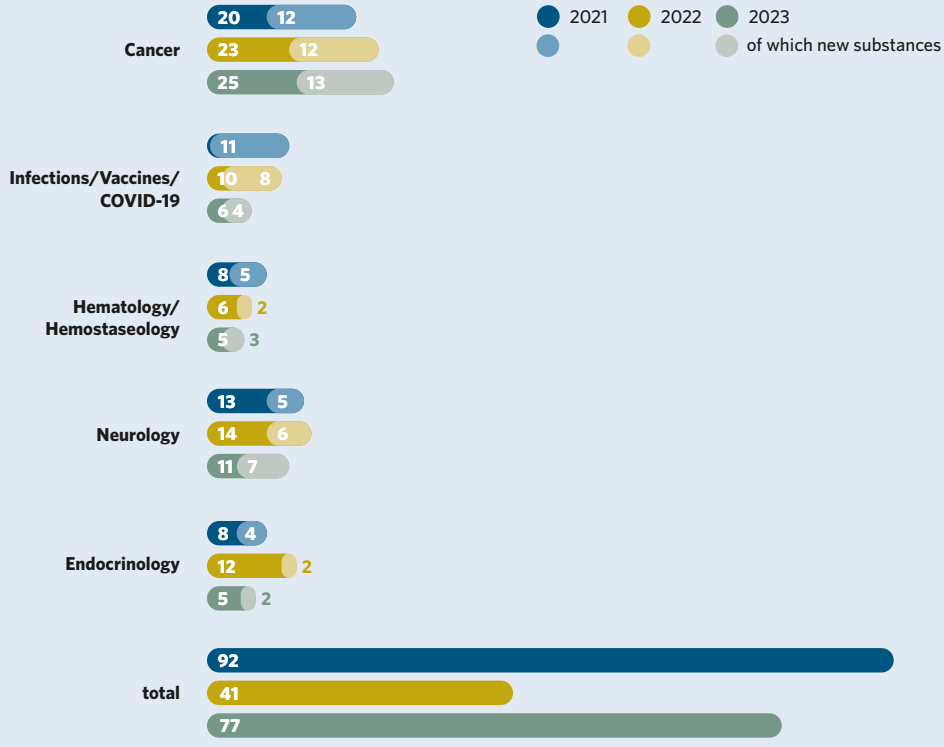
Innovative therapies have an impact on the individual/society, the economy and the public sector.

Source: Wert von Innovation im Gesundheitswesen, IHS 2021

Existing medicinal products have been tested and new ones have been developed to treat COVID-19. Currently, eight products are authorized in Europe for the treatment of COVID-19 (as of April 2024) (79).

The following examples show how innovative therapies can change the entire healthcare system and what opportunities they offer – especially for saving lives and enabling sick people to have a better quality of life again. **In the years 2021 to 2023, the EMA recommended 210 medicinal products for authorization, of which 134 with a new active ingredient.** Most innovations were in the areas of oncology, neurology, and infectiology (62).

Selected* innovations per therapeutic area



*Other: Cardiovascular system, dermatology, diagnostic agents, gastroenterology/hepatology, immunology/ rheumatology/transplantation, metabolism, ophthalmology, pneumology/allergology
Absolute figures

EMA Human medicines: highlights of 2023 (62)

7.1 Oncology

New oncological cases will continue to increase in the coming years due to the increasing proportion of older people. Although cancer is still the second most common cause of death in Austria, the chances of survival are increasing. This is mainly due to improved diagnostics (early detection programs, earlier diagnosis), medical progress, and new therapeutic methods (80).

Austria remains above the EU average, with a relative 5-year survival rate of 62 % over the period 2014–2018 (81, 82).

Over the past ten years, modern cancer medicine has helped patients gain a better quality of life. Cancer is increasingly becoming a chronic disease, is often curable in some areas today, and can be treated better and better thanks to new diagnostic and therapeutic options. In addition, those who are affected can actively participate in working life for longer. Oncological research and therapy are very diverse and complex. Today, it is estimated that there are more than 300 types of cancer (83). Factors such as shape, structure, genetic changes, and molecular properties influence tumor growth. In addition to common forms of treatment – surgery, radiotherapy, and chemotherapy – patients have access to biopharmaceutical forms of therapy, e.g. targeted and immuno-oncological therapies.

Oncology: Facts & Figures for Austria	
Known types of cancer	300
Number of cancer cases in 2022	402,805 of which 52 % women and 48 % men
Forecast of the number of cancer patients until 2030	460,000 (+ 15 % compared to 2022)
Cancer cases in 2022 in relation to the total population	4 %
Increase in prevalence from 2012 to 2022	26 % (women 25 % and men 28 %)
New cancer cases (incidence) 2022	44,764
Forecast of the number of new cases of cancer diagnosed each year in 2030	50,000
Most common cancer diagnosis in women	Breast, lung, colon, rectum
Most common cancer diagnosis in men	Prostate, lung, colon, rectum
Relative five-year survival (2014-2018)	62 %

Source: Statistik Austria - Krebsstatistik (81)

Oncology: Facts & Figures for Austria	
Survival disadvantage of people with cancer compared to the overall population	38 %
Approval of new medicines in oncology by the EU Commission 1995–2022	170
New approvals in oncology 2021 and 2022	60 (25 of which with new active ingredient)
Medicinal products in oncology in development	3,148

Source: Statistik Austria – Krebsstatistik (81)

Expenditure on cancer care

With 440 euros per capita, Austria is among the European leaders in spending on cancer care (EU average: 326 euros). The Netherlands and Germany are among the countries with the highest per capita health expenditure on cancer in the EU. In 2018, EU countries spent almost 170 billion euros on the treatment of cancer (84).

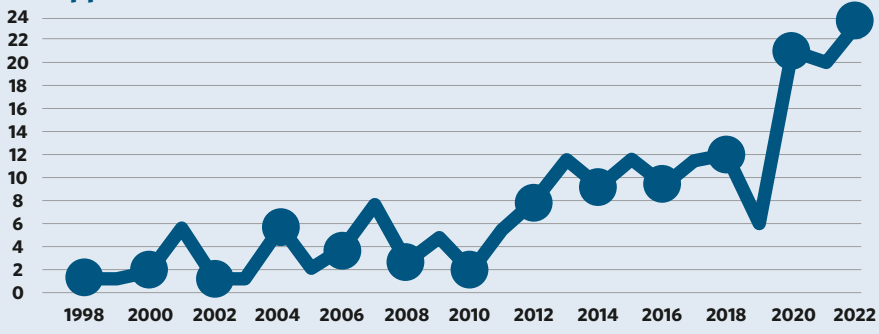
Direct health expenditure in Austria accounts for almost 60 % of total costs (EU average: 49 %), of which 22 % is for medicinal products for cancer (EU average: 15 %). Health-related productivity losses (7 % compared to 13 % in the EU) are below the EU average in Austria, while productivity losses due to premature death are on par (25 %) (82).

According to a study by the IPF (Institute for Pharmaceutical Economic Research), 100.53 million euros in treatment costs are financed annually by industry-sponsored clinical trials (based on the total expenditure on medical treatment, including all services within the framework of the clinical trial plan and not only on the clinical trial preparations) (80).

Medicinal products to treat cancer

- From 1995 to 2022, the EU Commission approved more than 170 new medicinal products in oncology (85).
- In the last two years, 60 new medicinal products against cancer have been launched in Europe – 25 of them with new active ingredients.
- Numerous other medicinal products are in development.
- In Austria, oncology (approx. 39 % of industry-sponsored clinical trials) is the most researched therapeutic area (see Chapter 4.2 Clinical Research) (86).

Number of medicinal products treating cancer recommended for approval

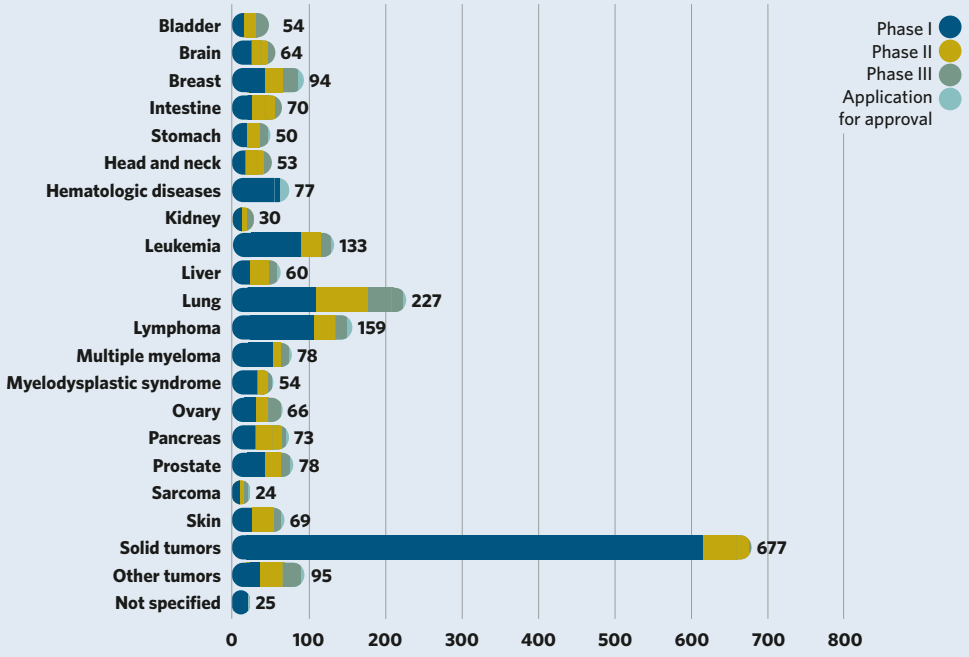


Source: Anzahl von der EMA zur Zulassung empfohlenen Krebsmedikamente (62)

Outlook

According to a survey by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), more than 3,148 medicinal products are currently in development worldwide for the treatment of more than 20 tumor types. New approaches such as genetic analyses (e.g. CRISPR), CAR-T therapies, viral therapies (application of mRNA technology), immunotherapies, or antibody conjugates are being pursued (87). Currently, more than 2,000 products are in clinical development worldwide (80).

Medicinal products and vaccines in development against cancer



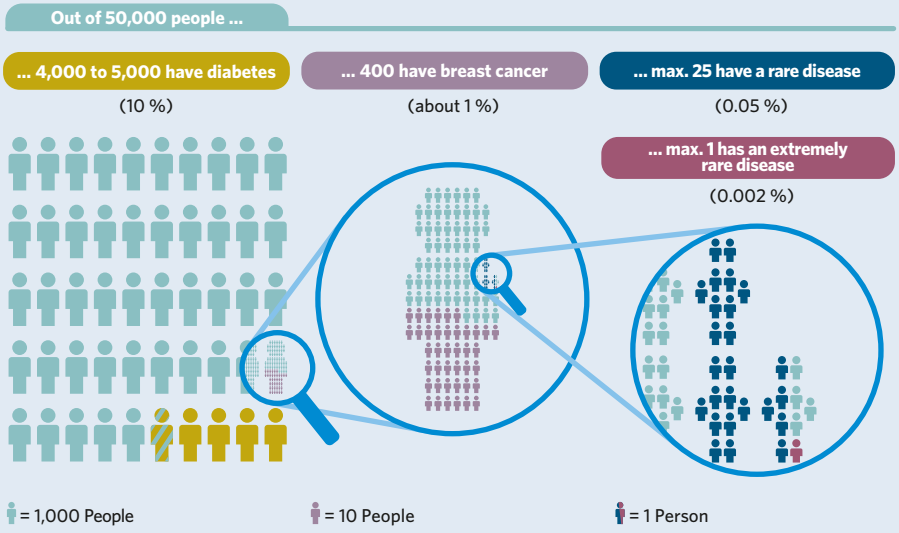
Source: PhRMA – Medicines in Development for Cancer – Report 2022 (88)

7.2 Medicinal products for the treatment of rare diseases

Rare diseases are life-threatening diseases or diseases leading to chronic disability, affecting less than 5 out of 10,000 people on average in Europe. Of the approximately 30,000 known diseases, more than 6,000 are rare diseases, over 50 % of which affect children. In Austria, around 500,000 people (equivalent to 6–8 % of the population) suffer from rare diseases, compared to an estimated 36 million in the EU.

The European Regulation on Orphan Medicinal Products (EC) No. 141/2000 was adopted in 2000 specifically to promote the research and development of orphan drugs by pharmaceutical companies. It offers companies reduced registration fees and a marketing right for 10 years (see Chapter 4.6). The prerequisite for this is an application for orphan drug status (= designation) at the EMA, which can be submitted at any time during the development of such a medicinal product before the application for marketing authorization is submitted. As with other medicinal products, the subsequent examination of the marketing authorization application is carried out in a centralized procedure by the Committee for Medicinal Products for Human Use (CHMP) (89–91).

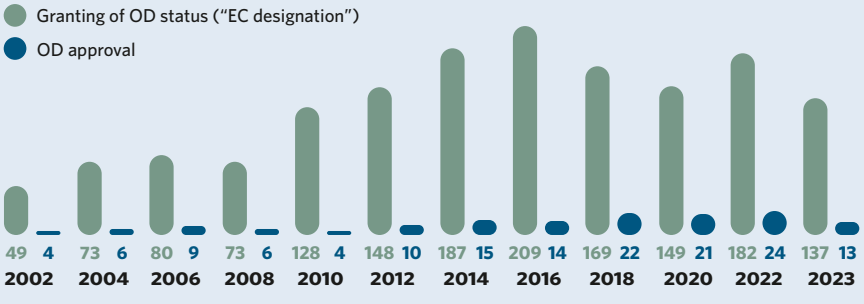
What is rare? A comparison



Source: PHARMIG

In the years 2000–2023, 4,393 applications for orphan drug status were submitted. 2,871 of them were granted, of which only 244 have received orphan drug approval so far. The high number of applications (4,393) reflects the gratifyingly high level of research activity in this area and shows that the incentives offered by the regulation are being accepted. However, the low success rate (244 approvals) also illustrates the high entrepreneurial risk. In 2023, 13 orphan drugs achieved approval (91). These include new medicines for rare diseases, including in the fields of hematology, oncology, and neurology, which have the potential to provide significant benefits to those affected and for which there are no other approved products to date (92).

Orphan drugs 2002 to 2023
Granting of status vs. approval



Absolute figures

Source: Annual report on the use of the special contribution for orphan medicinal products (92)

The National Action Plan for Rare Diseases (NAP.se)

The NAP.se was published at the end of February 2015 – aiming to improve the living conditions of all affected patients and their relatives. It was prepared on behalf of the Federal Ministry of Health by the NCSE (National Coordination Office for Rare Diseases) in cooperation with the Expert Group on Rare Diseases and the Strategic Platform for Rare Diseases. The starting points for the preparation were European requirements (e.g. recommendations, guidelines), the national needs assessment "Rare Diseases in Austria" (92), the structured exchange with national experts, as well as current national points of contact such as the Framework Health Goals, the Health Reform, or the Child and Adolescent Health Strategy.

The NAP.se combines plan and strategy and defines nine central thematic priorities that take into account both European recommendations and national requirements. The central element is the establishment of centers of expertise and their networking to pool knowledge and to be able to offer patients with rare diseases faster and better diagnoses as well as the best possible treatment options. The research and development of new medicinal products through better networked and bundled expertise is of great importance, especially for rare diseases. It is essential that the care of patients continues to be guaranteed close to home.

The NAP.se (89) as well as the evaluation of the report (2020) (93) and information on the centers of expertise (94) can be found on the website of the Ministry of Social Affairs (95).

Among other things, the NAP.se's evaluation report provides more clarity about further implementation and recommends continuous monitoring of the implementation of measures.

7.3 Plasma donation in Austria/ products made from blood plasma

There are numerous applications for medicinal products derived from human blood plasma (more than 60 authorized medicinal products), such as:

- the treatment of congenital and acquired immunodeficiencies,
- hematology including hemophilia,
- in the case of serious injuries and burns (for hemostasis and wound closure),
- in liver diseases,
- in severe infections (e.g. COVID-19; plasma-based therapy has been injected for treatment),
- in neurological diseases and
- in oncological diseases.

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

Blood plasma has been donated and processed in Austria for around 55 years and thus with the longest tradition in Europe.

Plasma donation and processing in Austria

- 24 Plasma Centers (96)
- Around 500,000 liters of donated plasma in 2019
- 58 liters of plasma per 1,000 inhabitants – Austria is one of the world's leaders in plasma collection and a leader in Europe
- Each plasma center contributes 1.5 to 5 million euros annually to the local economic output
- More than 400 employees in the Austrian plasma centers
- 2 plasma processing companies with a capacity of approx. 4 million liters of plasma per year (approx. 15 % of global capacity)
- Extraction of plasma components, fully integrated production of high-quality pharmaceuticals, and export to over 100 countries
- Creation of more than 5,000 jobs

7.4 Vaccinations

The widespread use of vaccines (excluding COVID-19) prevents 3.5 to 5 million deaths annually from diphtheria, tetanus, whooping cough, flu, and measles, according to the WHO. An increase in global vaccination coverage could prevent another 1.5 million deaths. The benefits of vaccinations are manifold (97, 98):

- They **protect vaccinated people** from **illness – more than 20 infectious diseases** can be prevented today by **vaccinations.**
- They **reduce long-term consequences** or later **disability.**
- **As a result,** vaccinations help to save **costs in the healthcare system** and are one of the **most cost-effective disease prevention measures** of all.

In the case of some vaccine-preventable diseases, one's own vaccination protection also contributes to the protection of the community. If enough people are vaccinated, so-called "herd immunity" is achieved. Then those who cannot be vaccinated (e.g. infants, the elderly, people undergoing immunotherapy, or cancer patients) will also be protected. The number of vaccinated people from which this herd protection takes effect varies depending on the disease.

In the long term, vaccinations can reduce epidemics and reduce or even eradicate diseases – such as smallpox or polio – through successful vaccination programs.

Calculations by the Institute for Pharmacoeconomic Research (IPF) for 2019 and 2023 show that vaccinations are also worthwhile for society and the healthcare system based on vaccinations against influenza, pneumococci, and human papillomaviruses (HPV) as well as from 2021 and 2023 against COVID-19 (99).

Vaccines – like all medicinal products on the market – are monitored for safety (see Chapter 6 Pharmacovigilance).

The vaccination system in Austria

The Austrian Vaccination Plan (available at www.sozialministerium.at) provides an overview of the vaccinations currently available. A distinction is made between vaccinations, which are covered by the public sector as part of the free vaccination scheme for children, and vaccinations, which have to be paid for by those who receive them but are recommended based on scientific evidence. For some vaccinations, such as meningoencephalitis (TBE), influenza, or pneumococcus, there is a subsidy from all health insurance companies. The COVID-19 vaccination is offered free of charge in Austria and is available for children aged 6 months and older, adolescents, and adults (100).

Life-Course Immunization (LCI) – Lifelong vaccination

Many vaccination programs focus on vaccinating children. However, scientific data shows that vaccinations are important in all phases of life and for all age groups.

In Austria, the free child vaccination scheme was introduced more than 20 years ago by the federal, state, and social insurance companies. The aim was to give all children living in Austria up to the age of 15 access to important vaccinations. This measure has made it possible to achieve herd immunity for many infections. The free vaccination program includes vaccinations against common diseases as well as against rarer, more severe diseases.

Maintaining vaccination protection through necessary booster vaccinations is important at any age. Depending on the stage and situation of life (e.g. pregnancy, breastfeeding, chronic diseases), additional vaccinations may be required. With increasing age, the prevalence of chronic diseases also increases, and thus the risk of complications and vaccine-preventable diseases with far-reaching consequences for the quality of life and independence of those affected. The creation of an Austrian-wide vaccination concept for adults with a focus on lifelong vaccination will therefore become more relevant in the coming years (99).

Vaccine pipeline

Research is also taking this development into account. An evaluation by Vaccines Europe (as of August 2023) shows that the pipelines of vaccine manufacturers are filled. There are currently 103 vaccine candidates in research and development, 83 of which are for adults (101). The most common vaccine candidates:

- COVID-19/SARS-CoV-2: 18 (also in combination with other coronaviruses)
- Influenza: 16
- Meningococcal diseases: 7
- Respiratory Syncytial Virus (RSV): 6

In addition, several vaccine candidates are in the pipeline that aim to combine these viruses (COVID-19, influenza, RSV).

Importantly, 42 % of vaccines under development are intended to combat diseases for which there is currently no vaccine. These include, for example, vaccines against Borrelia, which are transmitted by ticks, or against the Epstein-Barr virus. 15 vaccine candidates are directed against bacteria that are already resistant to antibiotics, four vaccines are being tested as infection-related therapeutic vaccines.

More than 80 % of the vaccines in manufacturers' pipelines are tested on adults and even old adults.

Overview of the vaccine pipeline in Europe

103 vaccine candidates in development
25 in phase III trials 7 in the regulatory approval process

42 %
of these are vaccines in **new vaccine indications**

16 are for **travelers**

63 % target **respiratory transmissible** infections

15 target **antibiotic-resistant** germs

81 %
are vaccines for **adults**

Source: Vaccines Europe pipeline review 2023 (101)

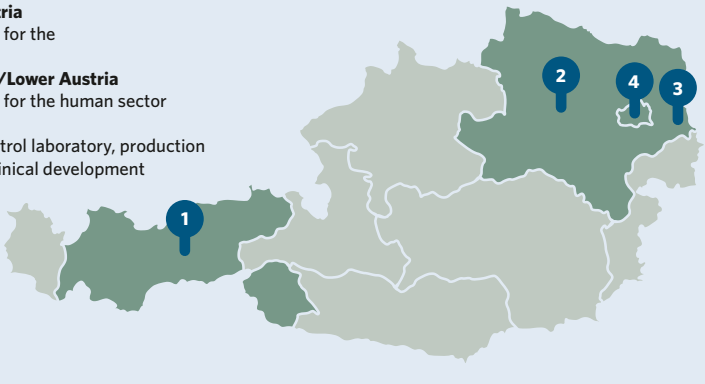
Vaccine production in Austria

There are only a few pharmaceutical companies in the world that specialize in the complex production of vaccines. Vaccines are highly complex pharmaceutical products that require lengthy manufacturing processes and a variety of control procedures. Austria plays a leading role in vaccine research and production.

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

Sites with vaccine research and production in Austria

1. **Kundl/T**
   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 laboratory, production release testing & clinical development



Source: OeVIH

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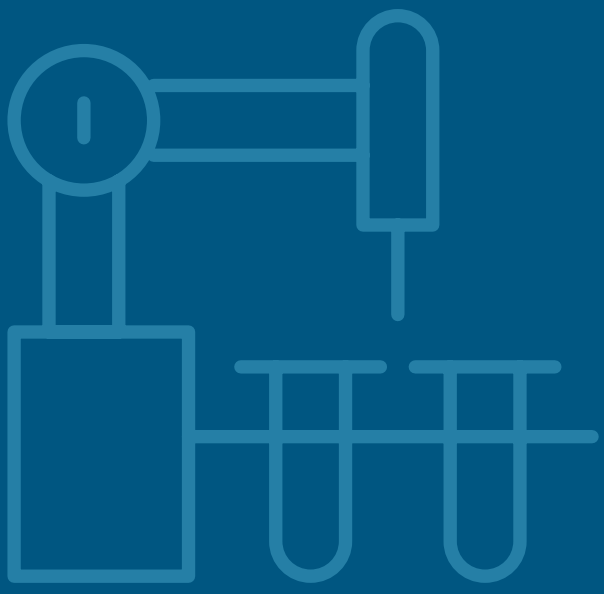
2.5 million jobs

in the pharmaceutical industry throughout Europe, the economic contribution is estimated at 1.4 % of GDP.

Exporting country

Austria is one of the export countries and has a positive trade balance in the pharmaceutical industry



8. Pharmaceutical Industry as an Economic Factor

The Pharmaceutical Industry Footprint in Europe

Source: Economic and societal footprint of the pharmaceutical industry in Europe (103)

The economic contribution of the pharmaceutical industry to EU economic output amounted to an estimated 206 billion euros in 2016. Of this, 100 billion euros was attributable to direct effects and 106 billion euros to indirect effects. This corresponds to around 1.4 % of total economic output (GDP). The pharmaceutical industry creates around 2.5 million jobs across Europe (which are above averagely qualified and female). This corresponds to approx. 0.9 % of all jobs in the EU (102).

8.1 Production in Europe

Pharmaceutical production in a European comparison

Country	Production in million euros	Euro 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
The 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	**1,453**	**158**	**9,061,000**
Poland	2,343	60	38,732,000

Source: EFPIA (61), Statistik Austria (Änderungen in Klassifikation im Vergleich zu Vorjahren) Eurostat 2023

In 2022, Switzerland, Belgium, Germany and Italy were responsible for the majority of pharmaceutical production in Europe. Switzerland recorded the highest production per inhabitant in terms of value (61).

8.2 Production in Austria

Pharmaceutical production in Austria, imports and exports

in million euros

Source: Statistik Austria – Güterproduktion 2022; EU-2027 EUROSTAT COMEXT International Trade (Änderungen in Klassifikation im Vergleich zu Vorjahren)

Austria is one of the export countries in the pharmaceutical industry: in 2022, Austria had a positive trade balance (1,136 million euros) (103).

8.3 Austria as a pharmaceutical location

The Austrian pharmaceutical companies, which either produce medicinal products themselves ("manufacturers") or import finished medicinal products into Austria ("depositors"), differ greatly in their scope of business. In addition to international corporations, small and medium-sized enterprises (SMEs) in particular shape the corporate landscape.The turnover ranges from a few 1,000 euros to 250 million euros per year.

*Includes companies that are active in the following areas: Research & development, distribution, supply, manufacturing

Sources: Haber, G. (2016): Life Sciences und Pharma: Ökonomische Impact Analyse; firmeneigene Veröffentlichungen 2013-2020

Each company makes a significant contribution to the Austrian economy as a whole and to the best possible healthcare. On www.pharmastandort.at , the performance of the industry is visualized, and it shows which companies are active every day in Austria as a business location.

8.4 PHARMA Industry Barometer

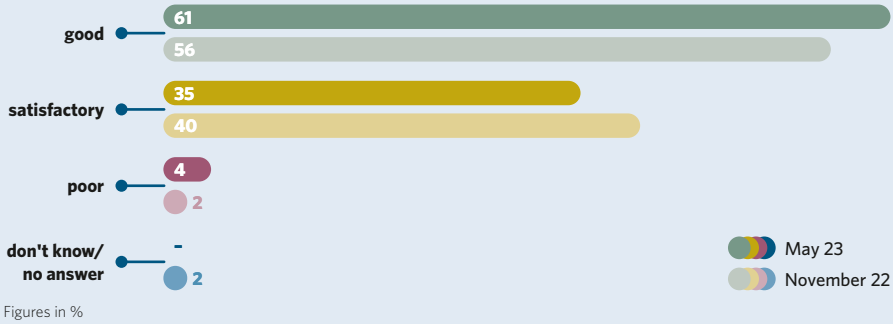
Assessment of the economic situation of harmaceutical companies in Austria

In autumn 2022 and spring 2023, the PHARMA Industry Barometer – a PHARMIG member survey to assess the current and future economic situation – was carried out (104).

- The **stability of the economic environment** and the **level of training of employees** are rated **pretty positively**
- The **dimensions of integration** into **health policy, pricing and Inflation** are **seen critically**
- **A good third of the companies** only **rate the current situation satisfactory**
- Around **the same number expect the situation to deteriorate** in the **six months** following the survey

Current economic situation of the company

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

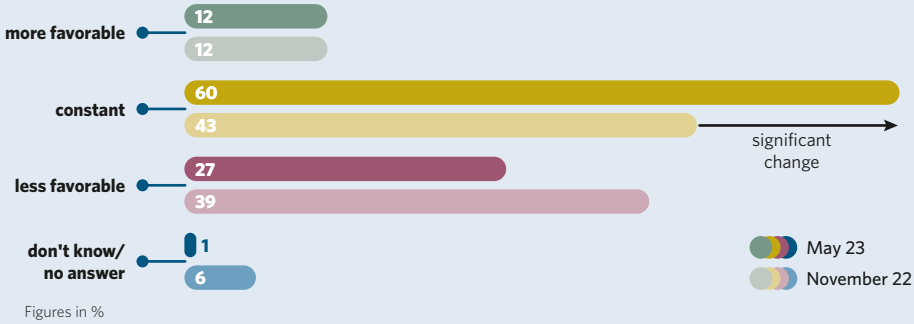


Figures in %

Source: PHARMA Branchenbarometer, 2022 und 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?"



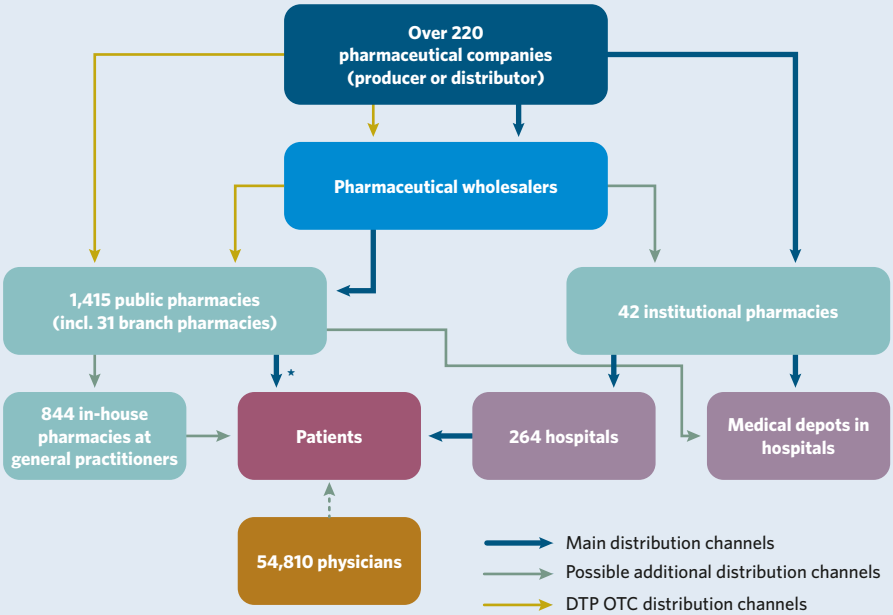
Figures in %

Source: PHARMA Branchenbarometer, 2022 und 2023; Peter Hajek, Public Opinion Strategies GmbH

8.5 Distribution of medicinal products

In Austria, medicinal products are supplied via the: pharmaceutical company – pharmaceutical wholesale – pharmacy – patient distribution chain.

Pharmaceutical supply structure 2022



*for OTC products as of 25.06.2015

Source: PHARMIG, STATISTIK AUSTRIA, Österreichische Apothekerkammer, Österreichische Ärztekammer (17, 29-31)

Around one third of the pharmaceuticals were sold to hospitals and two thirds to public pharmacies, the private practice sector (by value).

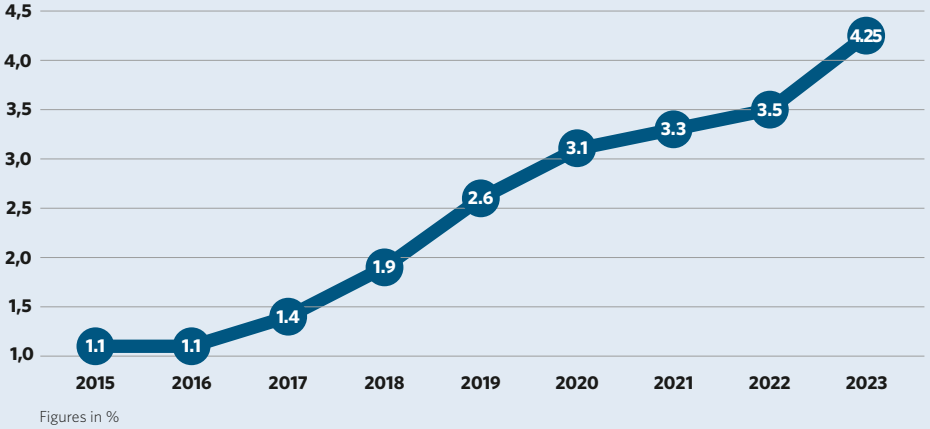
Parallel trade

If a medicinal product is not imported or exported within the EU by the manufacturer or marketing authorization holder, but in parallel by a third party via a distribution channel not defined by the manufacturer or marketing authorization holder, this is referred to as parallel trade. The prices of medicines are subject to direct or indirect government regulation in many EU Member States. This can result in price differences in the different countries for a particular medicine, which makes it attractive for parallel traders to buy medicines from low-price countries and import them into high-price countries. This parallel trade is legal due to the EU's free movement of goods, but also involves certain risks for supply.

Due to the incalculable flow of goods for manufacturers, delivery or even supply bottlenecks can occur. Legislation prescribes an adaptation to the national labeling for parallel-imported medicinal products, which is done by repackaging and inserting the leaflet in the respective national language. It is not uncommon for the medicinal products in question to be resold through several intermediaries until they finally reach the patients. These measures can increase the potential for counterfeits to enter the legal distribution chain. The savings for healthcare organizations that rely on such parallel imports are usually very small, as the majority of the margin remains with the parallel trader.

In Austria, the share of parallel imports has been rising continuously for several years: In 2023, the share of parallel imports was 4.25 % of the overall market. The private practice sector is much more affected with a share of 5.64 %. Compared to 1.28 % in 2015, the share of parallel imports has risen steadily in recent years. Meanwhile, parallel imports in the hospital market have tended to decline in recent years (1.57 % for 2023). Products for the treatment of the nervous system and from the field of oncology are particularly affected.

Parallel import in Austria



Figures in %

Source: IQVIA 2024

Austria is mainly 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 in the domestic market despite the marketing authorization holder's proven ability to supply. For this reason, the Ordinance on Safeguarding the Supply of Medicinal Products (BGBl. II Nr. 30/2020) created the possibility for the BASG to impose a temporary parallel export ban on products with distribution restrictions (105).

Distance selling – mail order business

Distance selling within the meaning of Section 59a of the Austrian Medicines Act (AMG) is the sale of over-the-counter medicines by public pharmacies using means of distance communication, e.g. by means of internet mail order.

With the implementation of the "Falsified Medicines Directive" (Directive 2011/62/EU), a uniform logo was created for all EU member states to identify authorized internet pharmacies, and mail order was thus also introduced in Austria.

For orders from an Austrian online pharmacy, look out for the Austrian flag symbol. Internet pharmacies that operate from other EU countries can also be recognized by the respective flag symbol. Legal internet pharmacies are only allowed to sell over-the-counter medicines in or to Austria.

Since June 25, 2015, distance selling in Austria has also been possible for Austrian pharmacies. The list of the AGES Medical Market Authority contains information on all mail-order pharmacies registered in Austria: versandapotheken.basg.gv.at

The legal regulations are regulated in the Distance Selling Ordinance.

8.6 Medicinal product supply

Despite all efforts in the distribution chain to ensure the supply of patients, there may be selective restrictions on the availability of medicines. According to the Ordinance on the Safeguarding of the Supply of Medicinal Products (BGBl. II Nr. 30/2020), marketing authorization holders have been required to report any restriction of the ability to distribute prescription medicinal products for human use since April 1, 2020 (105).

The notifications are published in the Distribution Restriction Register on the BASG website (medicineshortage.basg.gv.at) (106). Based on an evaluation scheme, the BASG subsequently also decides on a temporary parallel export ban for the reported products.

The reasons for supply bottlenecks are multifactorial and can be within or outside of the distribution chain:

- **continued pressure on prices** and consequently a migration of production to Asia as well as a concentration on a few manufacturers of active ingredients
- **Unexpected demand that cannot be calculated in advance**
- **Shortages of components necessary for the production of a product** (chemical components, intermediates, solvents, primary and secondary packaging)
- **Quality problems in manufacturing** (impurities in the production process, defects in packaging)
- **Challenges in the field of logistics and storage**
- **Overall longer delivery times for components** required in the manufacturing process (solvents and coatings, paper for packaging and package inserts, closures, plastic and glass containers)
- Ongoing **shortage of skilled workers** and **staff shortages** in production 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 or discussed at the Austrian and European, system, and company level and are aimed at the following areas (107):

- **Increasing production capacity** on the part of pharmaceutical companies as far as possible
- **Establishment of national and European inventory** for certain medicines that are particularly relevant to the supply or increase of these inventories
- **Improved connection of the Sales Restriction Register** to the doctors' practice software
- **Regulatory flexibilities** with regard to the import (transfer) of medicinal products with foreign-language instructions for use and also with regard to an adaptation of Section 4 (6) of the Prescription Obligation Act with the dispensing regulation for prescription medicines by pharmacies in emergencies
- **Introduction of a harmonized EU prevention and remedial system** to avoid duplication and to fully exploit the potential of existing data, such as those of the EMVS (European Medicines Verification System), the European Medicines Verification System (EMCS), the European Medicines Verification System, SPOR (Substances, Products, Organizations and Referentials Management Service) and the EMA IRIS platform
- **Increasing transparency in supply chains** through the use and networking of existing data, for example from the national organizations set up in the course of the Falsified Medicines Directive (in Austria the AMVS), from the EMVS, the SPOR, IRIS, and other sources
- **EU solidarity mechanism** in the event of critical shortages of essential medicines. This is based on voluntary action. If all other available options have already been exhausted, Member States can ask the relevant EU Steering Group (EMA) for support when procuring stocks of the medicinal product concerned.

- **EU Critical Medicines Alliance** as a measure to avoid supply bottlenecks. The group is to start its work on April 24, 2024 and will initially advise the European Commission for five years.
- **Strengthening the production of medicinal products** in Europe and Austria, although it should be noted here that the self-sufficient production of medicines would be difficult to realize due to global supply chains. From the point of view of companies from various industrial sectors (including the pharmaceutical industry), the main hurdles are:
  - » High operating costs in Europe due to higher personnel costs
  - » Lack of local suppliers (e.g. for important materials)
  - » High dependence on imports, especially for active pharmaceutical ingredients with high volume and low complexity

The topic of medicinal product supply had a high media presence in 2023 due to the supply bottlenecks in fall/winter 2022/23 and was one of the top priorities from a political point of view. The legal regulations in connection with the supply of medicines were therefore evaluated. At the end of 2023, a number of legal innovations were finally adopted, which have been in force since Jan. 1, 2024 (§§ 25a, 57a (3), 94k, 94l AMG and § 6a AwEG 2010). The question of whether there will be a national stockpiling obligation for selected proprietary medicinal products was not conclusively clarified in 2023.

According to Section 25a AMG, proprietary medicinal products to which non-safety-relevant modifications have been made may now be placed on the market by marketing authorization holders without this change until the respective expiry date of the medicinal product – unless this is not justifiable for reasons of medicinal product safety. Until now, only pharmacies were entitled to do so. Authorization holders were previously only allowed to place packs that did not yet contain the amendment on the market for one year.

Section 57a (3) AMG created the possibility of an ordinance on the stockpiling of active ingredients. Section 94k and Section 94l AMG regulate the bearing of the costs of any obligation to stock selected medicinal products or active ingredients.

The new § 6a AwEG 2010 makes it easier to bring in proprietary medicinal products in the event of supply bottlenecks. The prerequisite is that the medicinal product has been authorized or manufactured in the EEA, that the demand cannot be met by a medicinal product that is authorized and available in Austria, that the medicinal product is needed to bridge supply bottlenecks and to ensure the supply to the patients.

Medicinal product prices on the Austrian market have been declining for years: a pack that cost 10 euros in 1996 will cost

6.17 Euro

in 2023

The consumer price index (CPI) is developing in opposite direction: the inflation rate is

2023 + 7.8 %

9. Pharmaceutical Market

9.1 Pricing of medicinal products

In Austria, the pricing of medicinal products is regulated by law. The corresponding basis for this is the Price Act 1992 (for all medicinal products for human use) and the General Social Insurance Act (ASVG for inclusion in the Reimbursement Code). The Price Commission of the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) is responsible for setting the prices of medicinal products (108).

The price basis of a medicinal product is the manufacturer's factory or depot selling price (FAP/DAP). The respective surcharges (wholesale and pharmacy surcharge – regulated by law by graduated maximum surcharges) and VAT are calculated based on this price. The FAP/DAP can be freely determined by the company authorized to distribute, however the BMSGPK must be informed of this price.

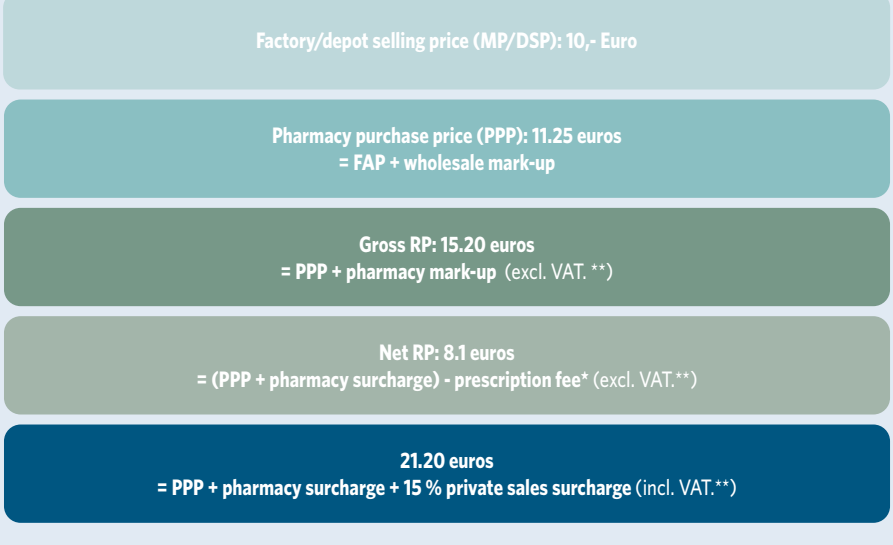
Medicinal product price

- **Factory/Depot Selling Price (MP/DSP):** Manufacturer/Depositor › Wholesale
- **Pharmacy purchase price (PPP):** Wholesale › Pharmacy

In case of REFUND:
- **Health Insurance Price (RP):** Pharmacy › Social Insurance Institutions

For PRIVATE PURCHASE:
- **Pharmacy sales price (PSP):** Pharmacy › Private customer

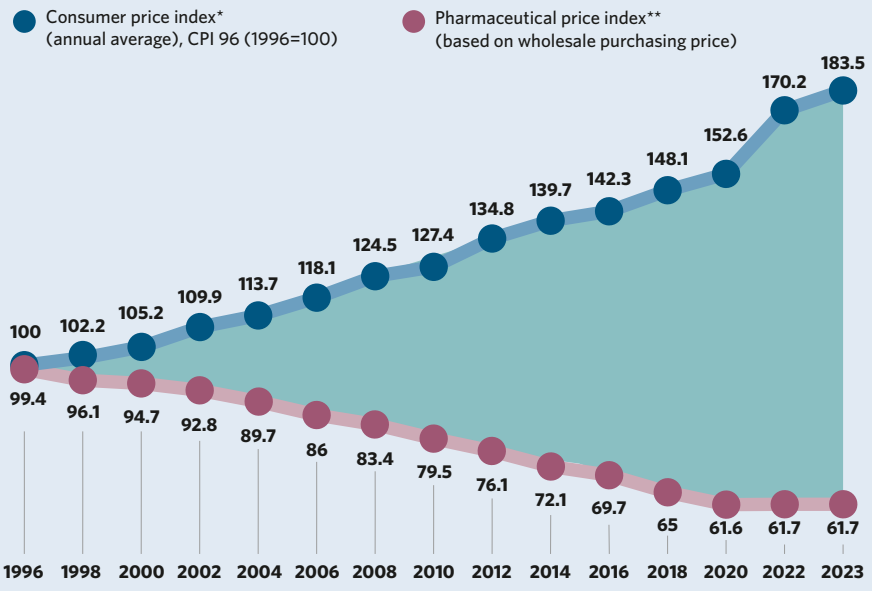
Pricing example



* Prescription fee since 01.01.2024: 7.1 euros; ** VAT since 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: Berechnet nach Angaben von STATISTIK AUSTRIA und IQVIA

The prices of medicinal products already on the Austrian market have fallen every year since 1996. A fictitious package of medicinal products, which cost 10 euros in 1996, only cost 6.17 euros in 2023. Due to the legal provisions, automatic inflation adjustment is not permitted for medicinal products. Otherwise, the price of the fictitious package would be 18.4 euros today. In 2023, the inflation rate was +7.8 % (109).

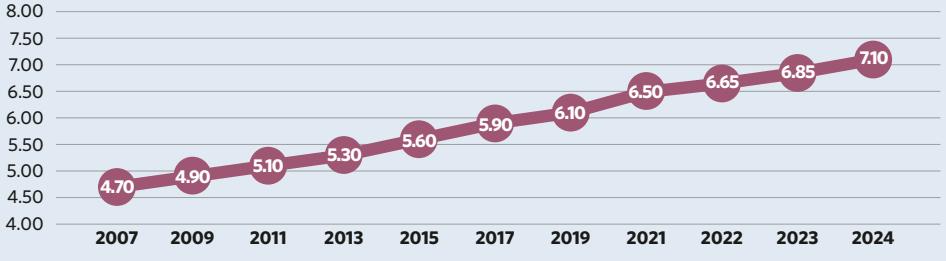
Consumer price index and medicinal product price index are widening from year to year. The price of medicines is falling continuously, while the consumer price index is rising every year.

The health insurance price of 45.6 % of all reimbursable* packages (calculated by IQVIA based on sales) is below the prescription fee for 2023 (in the amount of 6.85 euros) (110).

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

The annual adjustment of the prescription fee is regulated by law. In the period 2004–2024, the prescription fee increased by around 63 %. The prescription fee means revenues of 451 million euros for health insurance in 2022 (13).

Development of prescription fees 2004–2024



Values in euro

Source: oesterreich.gv.at (111)

In addition to the general exemption from the prescription fee for social reasons, 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) since January 2008. If this threshold is exceeded, insured persons and co-insured relatives are exempt from the prescription fee for the remainder of the calendar year (112).

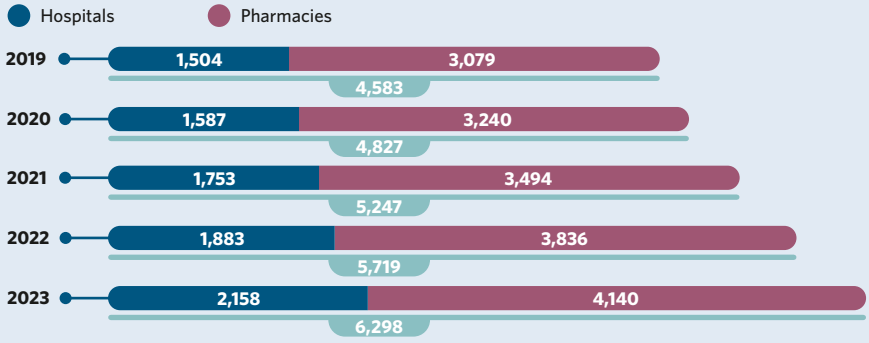
9.2 Hospital and Pharmacy Market

In 2023, the Austrian pharmaceutical market reached a value volume of 6.3 billion euros and a volume of 242 million packages. This represents growth of +10.1 % in terms of sales and +1.3 % in terms of volume.

From the point of view of manufacturers and depositors, the Austrian pharmaceutical market is divided into two segments:

- **Hospital market** (intramural sector)
- **Public pharmacies** and **doctors in charge of in-house pharmacies** (extramural sector)

Pharmaceutical sales (based on manufacturer price, MP*)



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

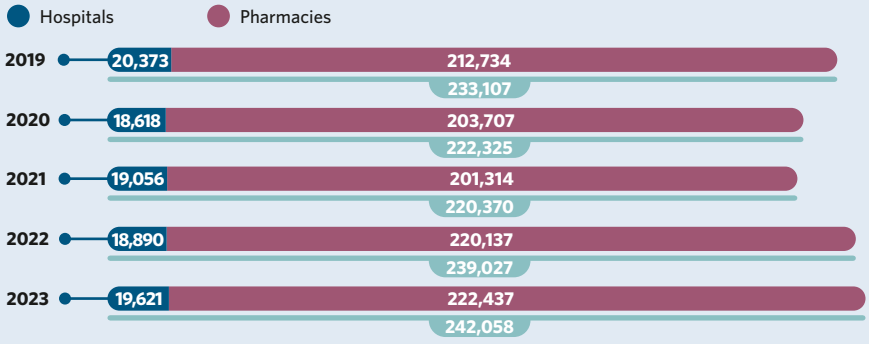
Source: IQVIA DPMÖ next level adaptierter Datenerfassung (inkl. RX Direktgeschäft)/ DPMÖK

Both the pharmacy market and the hospital market grew in value and volume in 2023 compared to 2022.

- **Pharmacy market:** +8.2 % by value in euro terms in turnover and +1.1 % by volume by pack (public pharmacies)
- **Hospital market:** +14.6 % in terms of value in euro terms in turnover and +3.8 % in volume terms in terms of packs

In 2023, 242 million packs were sold in Austria, of which around 8 % went to hospitals (institutional pharmacies) and around 92 % to pharmacies in the extramural sector.

Sold packs



Figures in thousands

Source: IQVIA DPMÖ next level adaptierter Datenerfassung (inkl. RX Direktgeschäft)/ DPMÖK

In 2023, there was an increase of +1.3 % in packs sold compared to 2022 .

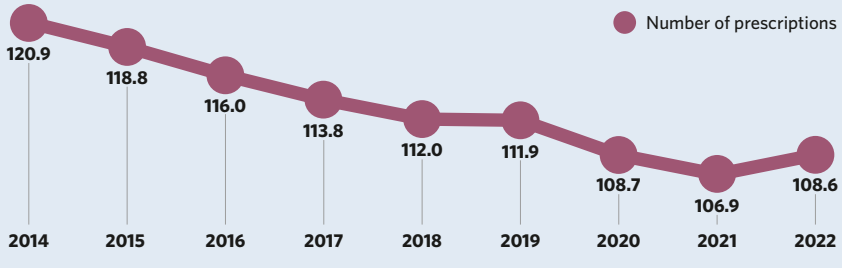
The growth of the prescription-established market at the level of + 7.8 % (measured in terms of revenue in 2023) is influenced by a variety of elements, according to calculations by IQVIA:

- **Price changes** are understood to be changes in the price of a certain product that has already been launched on the market compared to the previous period. In 2023, price changes have a marginal impact on market development by 0.1 %.
- **New launches** include those products that contain new active ingredients in the first year after market launch. These products replace previous forms of therapy or enable new therapies for the first time. New launches will have a small impact on market growth of +0.5 % in 2023 – a similar development to 2022 (0.4 %).
- **Structural effects** include factors such as changes in prescribing habits, replacement and expansion of previous forms of therapy, new dosage forms, and increases in volumes, etc. In 2023, structural effects amounted to +7.2 %.

9.3 Prescription trend

The number of prescriptions for therapeutic products decreased annually in the period from 2014 to 2021. In 2022, it fell by almost 10.2 % compared to 2014, but rose slightly again compared to 2021.

Number of reimbursed prescriptions per insured person

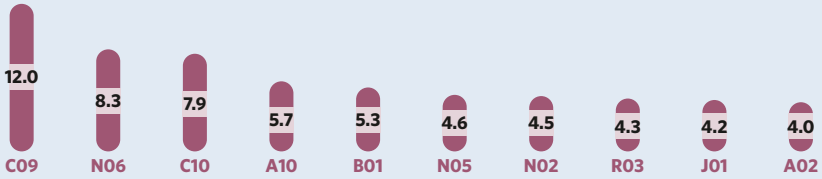


Figures in million euros

Source: Österreichische Sozialversicherung SV (13)

9.4 Pharmaceutical consumption by indication groups

The most frequently prescribed therapeutic subgroups ATC-level 2*, 2022



*ATC Code: Anatomical Therapeutic Chemical Classification System of the WHO
Figures in million

C09 Agents acting on the renin-angiotensin system
N06 Psychoanaleptics
C10 Agents affecting lipid metabolism
A10 Antidiabetic agents
B01 Antithrombotic agents
N05 Psycholeptics
N02 Analgesics
R03 Agents for obstructive respiratory diseases
J01 Antibiotics for systemic use
A02 Agents for acid-related diseases

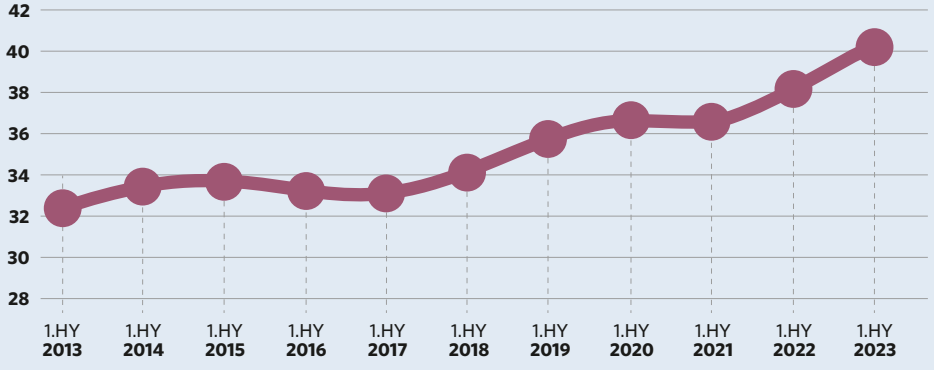
Source: Österreichische Sozialversicherung SV (13)

Around 60 % of all prescriptions are in the 10 indication groups with the highest number of prescriptions.

The most commonly prescribed medicinal products according to the ATC system are those with an effect on the renin-angiotensin system (e.g. for high blood pressure), psychoanaleptics (against mental illnesses, e.g. depression), and those that influence fat metabolism. These 3 indication groups with the highest number of prescriptions account for almost 26 % of all prescriptions (13).

9.5 Generic medicinal products

Prescribed generic products in the reimbursement market



Figures in %

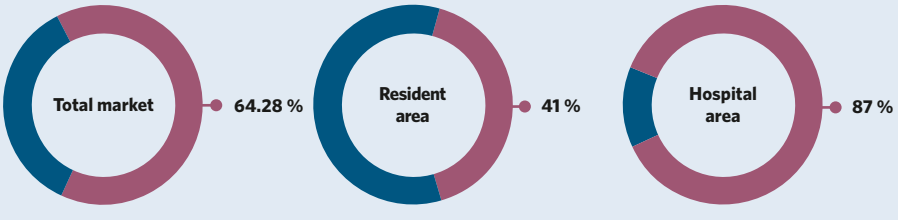
Source: ÖGK - Allgemeines aus dem Erstattungskodex (EKO) (113)

In the first half of 2023, generic medicines accounted for more than 40 % of all packages dispensed in the established market (113). Looking only at the replaceable market, the share of generics is 59.9 %, i.e. more than every 2nd pack dispensed is a generic (source: SV 2023) (see Chapters 4.1, 10.3).

9.6 Biosimilars

In Austria, 55 approved biosimilars (for 18 different active ingredients) were available for the treatment of diseases such as cancer, autoimmune diseases, growth disorders, osteoporosis or blood clotting at the end of 2023 (approvals: 82 biosimilars for 21 active ingredients, as of 12/2023) (114).

Biosimilars accounted for 64.28 % of the total biosimilar-eligible market in Austria (measured by sales) in 2023: in the private practice market, this share is around 41 % and in the hospital market 87 %.



Figures in %

Source: IQVIA, Biosimilarsverband Österreich, 2023 (114)

In Austria, the generic and biosimilar price rule also leads to significant price reductions for the original supplier (see Chapters 4.1, 10.3)..

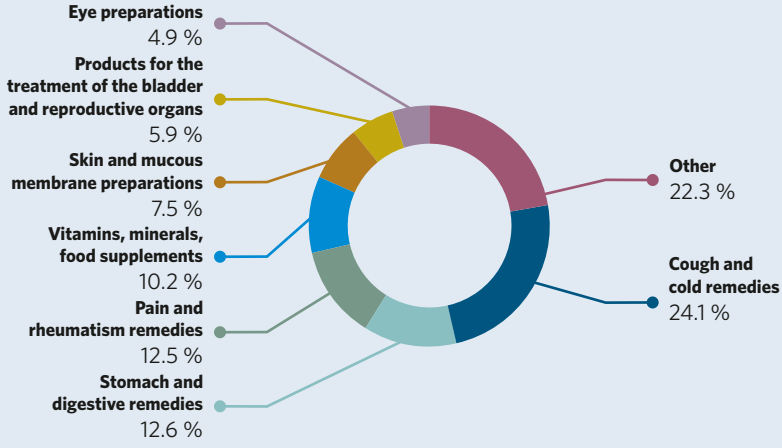
The introduction of biosimilars and the associated price reductions of reference medicines in the retail and hospital sectors have saved around 1.18 billion euros (FAP) over the last 14 years. By 2027, Austria has a further considerable savings potential of around 330 million euro (FAP) (consumption and price simulation study) (115).

9.7 Self-medication market

In terms of value, the OTC market increased by +6.5 % in 2023 compared to 2022 to 1,471 million euros (AVP). The average growth since 2020 is 5.6 % per year. In terms of volume, after an increase of 9.4 % in 2022, there was a decrease of 0.2 % in 2023 (116).

Medicinal products for the treatment of coughs and colds will continue to be the largest indication group in 2023, accounting for 24.1 % of sales in AVP. The growth rate compared to 2022 is +6 %. The group of ophthalmology preparations showed the strongest growth in 2023 at 11.3 % (116).

Indication groups in self-medication (basis AVP) 2023



Figures in %

Source: IGEPHA Jahresbericht 2023 (116)

Medicinal products for self-medication, so-called "over-the-counter" (OTC) medicinal products, are effective, safe and make sense from a health economic point of view. They are therefore an integral part of healthcare and the treatment of many diseases. About one in four medicines dispensed in pharmacies in Austria is such an over-the-counter OTC medicine.

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The Reimbursement Code (EKO) is a

“Whitelist”

and enables medicinal products to be prescribed in compliance with defined rules.

The listed products undergo a pharmacological, medical-therapeutic and health-economic evaluation and impress with their

Benefits and costs.

10. Pharmaceutical Reimbursement of Medicines by Social Security

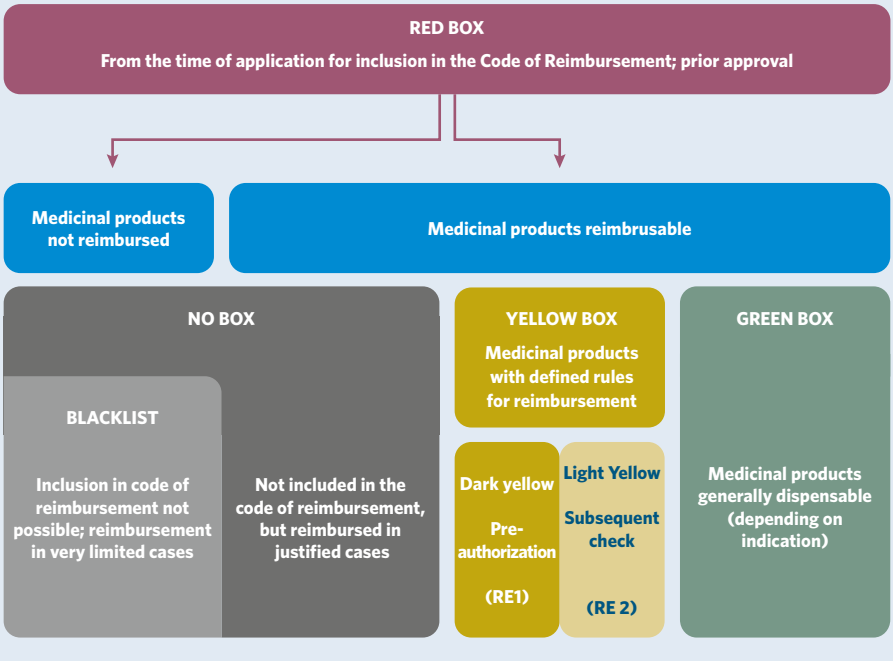
The majority of social security benefits are subject to the principle of benefits in kind. The scope of medical treatment at the expense of social security is defined by law as follows: "It must be sufficient and expedient, but must not exceed what is necessary." (§ 133 ASVG)

10.1 The Reimbursement Code (EKO)

The ASVG regulates access to medicinal products for all insured persons in Austria after approval by the social security system. The Reimbursement Code represents a "whitelist" and thus allows either "free prescription" (without prior chief and control physician approval = green box) or sets rules (specific use – "regulatory text") for approval by the chief and control physicians (yellow box of the EKO). The products listed in the EKO undergo pharmacological, medical-therapeutic and health-economic evaluation (see Chapter 10.2) – in other words, they are convincing both in terms of their benefits and in terms of costs. On 1 January 2005, the Reimbursement Code replaced the list of therapeutic products used until then (117).

The EKO is divided into three areas (also called boxes):

The box system – simplified presentation



Source: FOPI - Erstattungskodex (EKO) und Arzneimittel-"Boxensystem" (118)

- **The green box** includes those medicinal products that may be dispensed either generally or under certain conditions in the quantity specified as freely prescribable. The authorization 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 area are decisive for price fixing. If a higher price is sought for the specialty medicinal product applied for, added therapeutic value must be demonstrated.

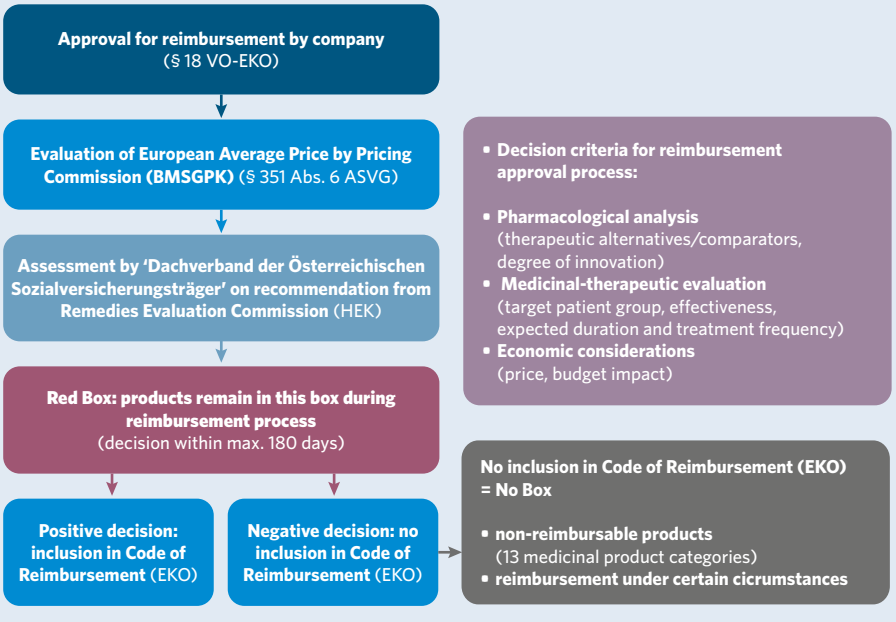
- **The yellow box** includes those medicinal products that have a significant additional therapeutic benefit for patients and that have not been included in the green area for medical and/or health economic reasons. For a medicinal product in this area, a maximum of the EU average price determined may be charged. The costs will only be covered by the health insurance institutions if the medical authorization has been obtained of the chief and control medical service of the social insurance (RE1 = dark yellow box). For individual medications in this box, the intake of which relates to a specific use, the umbrella organization accepts a subsequent check of compliance with the specific use on the basis of the documentation of the treating physician (RE2 = light yellow area) instead of the chief physician's approval.

- **The red box** includes those products for a limited period of time whose inclusion in the reimbursement code has been applied for. The price of the proprietary medicinal product must not exceed the EU average price. The costs are only covered by the health insurance institutions if they have been approved by the chief and control medical service of the social insurance system.

All other medicinal products that are not included in the Reimbursement Code are only paid for by the social security institutions in justified individual cases and if a chief physician's license has been obtained. Authorization must be granted via the Medicinal Products Licensing Service ABS.

10.2 Application for inclusion in the reimbursement process (VO-EKO according to § 351 ASVG)

On the basis of the ASVG (§ 351c ff.), the Rules of Procedure for the Publication of the Reimbursement Code (VO-EKO) regulate in detail the process, the requirements and the deadlines for the inclusion of medicinal products in the Reimbursement Code. The admission procedure is an administrative procedure and is carried out by means of an electronic application. The medicinal products contained in the Reimbursement Code are published at the beginning of each year in printed form and as downloads (119), and the monthly changes are published on the internet under www.ris.bka.gv.at (120).



Source: Sozialversicherung - Arbeitsbehelf Erstattungskodex (121)

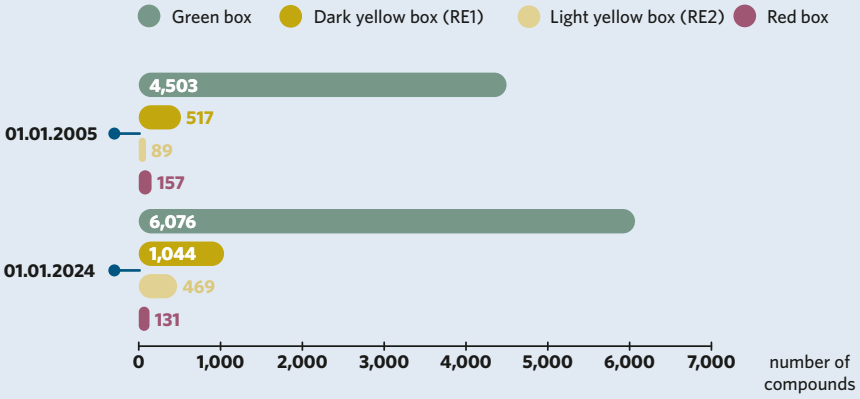
Certain groups of medicinal products are generally excluded from inclusion in the EKO (Official Announcement No. 34/2004; list of non-reimbursable categories of medicines in accordance with § 351c (2) ASVG) and must usually be paid for by the patients themselves, unless the assumption of costs has been approved in advance by the chief medical service (e.g. medicines that are mainly dispensed in hospitals, contraceptives, etc.). (121).

Remedies Evaluation Commission (HEK)

The Remedies Evaluation Commission is the advisory body of the 'Dachverband der Österreichischen Sozialversicherungsträger' (DV). All applications for the inclusion (including amendments) of a proprietary medicinal product in the Reimbursement Code must be submitted to HEK. The HEK must also be consulted if the DV intends to amend the Reimbursement Code on its own initiative. The HEK makes a written recommendation to the DV.

The members of the Remedies Evaluation Commission and their deputies can be found on the website of the Austrian Social Insurance (122).

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



The data was taken from the list of goods published by the Austrian Chamber of Pharmacists | as of 01.01.2024
* by the package – pharmaceutical registration numbers

Source: Österreichische Apothekerkammer (42)

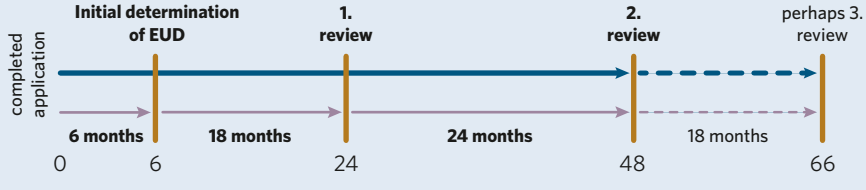
As of Jan. 1, 2024, a total of 7,720 packs were listed in the EKO, compared to 5,266 packs (42) when it was introduced in 2005.

10.3 Special price regulations through social security

EU average price

In the course of the 61st amendment to the ASVG, the EU average price was newly regulated as the maximum limit for reimbursement prices. The Price Commission determines the EU average price from the prices of the EU Member States reported by the companies. As long as the EU average price cannot be determined (EUD, the EU average price can be determined if the FAP/DAP is available in at least two EU member states except Austria), the price reported by the company entitled to distribute is provisionally valid. The EU average price must be determined by the Price Commission within six months of the application being submitted.

Gesundheit Österreich GmbH (GÖG) can be called in for this purpose. After the initial price determination, the Price Commission must again determine an EU average price after 18 months and after a further 24 months; a new determination is possible after a further 18 months.

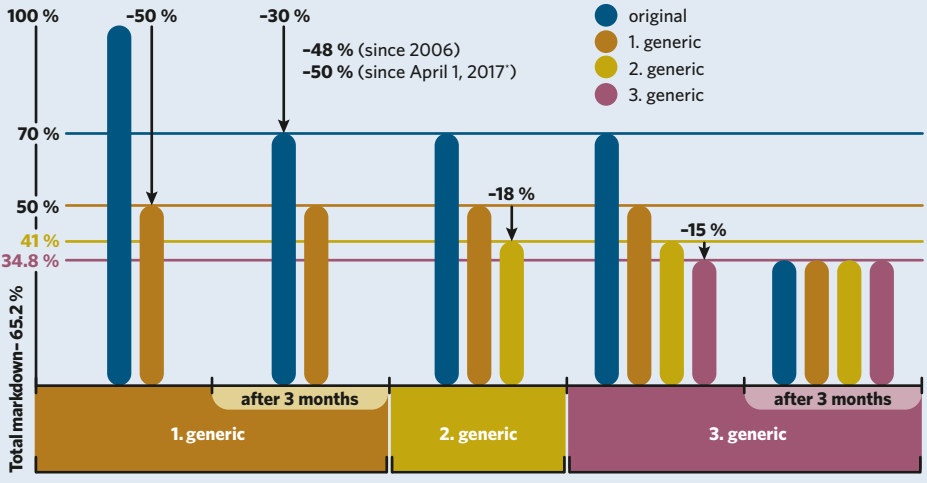


*EUD= EU average price

Source: Sozialversicherung - Arbeitsbehelf Erstattungskodex (121)

Generics

The 2017 amendment to the ASVG (Federal Law Gazette I 49/2017) amended the previous price regulation for the inclusion or retention of interchangeable products with the same active ingredient (original and successor products) (Section 351c (10) (1) ASVG, for generics see also Chapter 4.1):

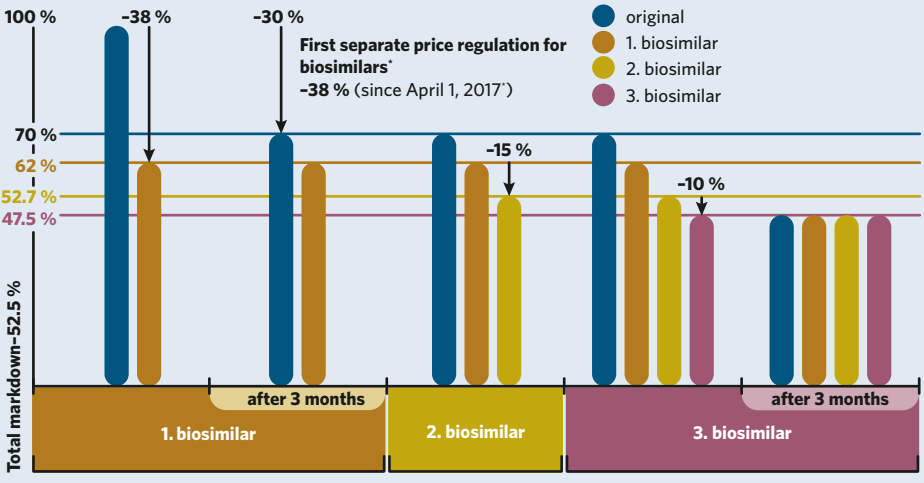


**ASVG amendment from BGBl. No. I, 49/2017 § 351c Para. 10 in force as of 1 April 2017, limited until 31 December 2023

Source: ASVG/VO-EKO/Ökonomische Beurteilungskriterien der HEK

Biosimilars

With the 2017 amendment to the ASVG, a separate price regulation for biosimilars was laid down in the ASVG for the first time (§351c para. 10 Z2 ASVG, for biosimilars see also Chapter 4.1), which makes it easier to plan market entry:



*ASVG-Novelle aus BGBl. Nr. I, 49/2017 § 351c Abs. 10 in Kraft per 01.04.2017; befristet bis 31.12.2025 (BGBl. I Nr. 200/2023)

Source: ASVG/VO-EKO/Ökonomische Beurteilungskriterien der HEK

Price range

Due to price divergences of individual active ingredients within the green box, a price range was set for alignment for the years 2017, 2019 and 2021. The price of the affected medicinal products with the same active ingredient (see the respective announcement of the then Main Association) in the green box may not exceed 30 % above the price of the cheapest proprietary medicinal product of the same active ingredient on the reference date (1 February of the review year) (2017 amendment to the ASVG, § 351c para. 11). The price had to be lowered accordingly in October of that year. In return, cancellation procedures for these products were omitted for economic reasons until April 1, 2022.

In 2023, there will be a new, adapted application with a corridor of 20 % to the cheapest medicinal product with the same active ingredient in the same or very similar dosage form. The decisive factor within an active ingredient is the respective key strength (the most frequently prescribed). The price reduction is necessary to a maximum of the amount of the prescription fee, i.e. proprietary medicinal products whose price is below the prescription fee are exempt from this regulation. However, these are used to determine the maximum price. In return, the cancellation procedure for these products was omitted for economic reasons until December 31, 2023.

A new implementation of the price band in 2025 was decided with the 2023 amendment to the ASVG (BGBL. 200/2023).

According to the 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 an investment. (123).

Source: Parlamentarische Anfragebeantwortung 8908/AB, IQVIA

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

The special provisions (§ 351c (9a) ASVG) that have been in force since the 2017 amendment to the ASVG for proprietary medicinal products that are not listed in the EKO (see Chapter 10.1), but are reimbursed in certain exceptional cases (Section 351c (9a) of the ASVG were tightened in 2022 (BGBL. 32/2022). For these medicinal products, if the annual turnover exceeds 750,000 euros, a partial amount must be repaid by the pharmaceutical companies to the social security system. The price commission determines the EU average price as a guideline. If the FAP offset against social security exceeds the EU average price, there is an obligation to repay these proprietary medicinal products in excess of the difference (121).

Price increases

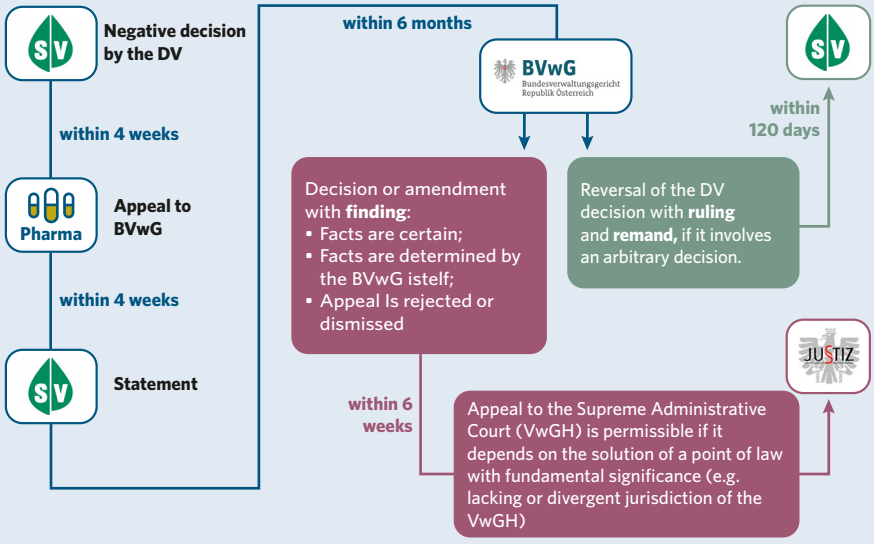
Price increases for medicinal products are regulated by law in a very restrictive manner (e.g. max. every 24 months) and are only possible to a very limited extent. The umbrella organization has a wide margin of discretion in this regard (121).

10.4 Federal Administrative Court

The Federal Administrative Court (BVwG) is responsible for appeals against a decision of the umbrella organization of Austrian social security institutions. An appeal must be filed within four weeks of notification of the decision via the www.sozialversicherung.at Internet portal. The appeal has suspensive effect for the most part. The decision is made by the 5-member Senate (deliberation and vote of the Senate not public) (124).

The BVwG's findings are published in the Federal Legal Information System (RIS) under www.ris.bka.gv.at.

Process flow



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

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Since 1970

the VHC includes industry-wide compliance regulations.

In addition to general

Principles

binding rules for information on medicinal products and advertising measures as well as for transparent cooperation with the medical profession and patient organizations are laid down.

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 products, thereby contributing to the correct use and safety of them. The exchange of the respective empirical values is also an essential aspect, which also flows into the further development of therapy concepts. All these aspects require a reasonable basis for cooperation between several partners in the healthcare sector. When working with health professionals or institutions, it is important to focus on the respective scientific context and to design the framework of the cooperation in a comprehensible and transparent way.

This is exactly where industry-wide compliance regulations come in: the pharmaceutical industry has done pioneering work in this field. Since 1970, the CoC has been making a valuable and important contribution: The regulations specify legal requirements with the aim of protecting the freedom of health professionals to procure, decide and treat from unfair influence and thus ultimately strengthen the trust of the public and patients in the necessary cooperation.

In addition to general principles, the PHARMIG Code of Conduct lays down binding rules for information on medicinal products and advertising measures. It comprehensively regulates cooperation between pharmaceutical companies and healthcare professionals, institutions such as hospital operators or medical societies, and patient organizations. The aim is to make this cooperation fair and transparent.

The pharmaceutical companies that have submitted to the CoC show a high sense of responsibility and send a clear signal of integrity. In order to meet this responsibility, there are compliance functions that provide support within the company as business partners with integrity.

Companies live ethical responsibility

Compliance is the responsibility of all employees and divisions and primarily concerns:

- **The promotion** of ethical and **lawful behavior** between **the pharmaceutical industry, business partners** (such as healthcare professionals) and **stakeholders**
- **Ensuring fair competition** within the **pharmaceutical industry**
- **Ensuring that doctors** are able to provide information about **therapeutic options**
- **Consistent adherence** to the established **principles of conduct** and their **monitoring**
- A **compliance program** implemented in **all departments** to protect the **integrity of the company**

Transparency creates trust

Since 2014, the CoC has also included provisions on how pharmaceutical companies disclose non-cash benefits when they work with doctors, hospitals or support the work of patient organizations. In principle, the individual disclosure of non-cash benefits resulting from this cooperation should be sought. For individual disclosure, there must be a basis under data protection law. Depending on the situation, this can consist of consent or the overriding legitimate interest. In the event that this is not the case, the publication must be made in aggregated form.

The disclosure takes place annually on June 30 on a publicly accessible website. More information on the Transparency Initiative can be found at:
www.pharmig.at/pharmaindustrie/transparenz

Living industry culture

The voluntary self-regulation through the PHARMIG Code of Conduct testifies to a great sense of responsibility and the clear will of PHARMIG member companies to live a high industry culture.

In order to quickly resolve differences of opinion regarding the CoC provisions out of court before a panel of experts, it is possible to conduct so-called CoC proceedings before the CoC Committees of Experts of First and Second Instance.

Non-members and third parties also have the opportunity to file complaints about alleged violations of the CoC. In this case, a written agreement ensures that the parties to the proceedings are subject to uniform rules. Under certain conditions, complaints can also be submitted anonymously. In the interests of legal certainty, the results of the CoC proceedings will be published in anonymized form on www.pharmig.at/der-verband/pharmig-verhaltenscodex.

Flow chart – Procedure of technical committees VHC I and II instance available at:
www.pharmig.at/der-verband/pharmig-verhaltenscodex

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12. Laws and Regulations

The most important legal and other regulations that apply to the development, manufacturing, testing, approval and distribution of medicinal products. For more information on national and EU legislation, please visit www.pharmig.at

Law	Regulatory areas
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
Pharmaceutical Operating Regulations *Arzneimittelbetriebsordnung (AMBO)*	Good Manufacturing Practices, Good Distribution Practices, Pharmaceutical Quality Assurances
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)*	Act against Unfair Competition, Advertising Behaviour in Relation to Consumers and Competition
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 the procurement of services (award procedure) in the public sector
Federal Constitutional Act *Bundesverfassungsgesetz (B-VG)*	Basic structure of the Austrian constitution: including four basic principles, distribution of competences between the federal and state governments
Federal Administrative Court Act *Bundesverwaltungsgerichtsgesetz (BVwGG)*	Organization of the Federal Administrative Court

Law	Regulatory areas
Delegated Regulation (EU) 2016/161	Safety features on the packaging of medicinal products for human use
EU code on medicinal products for human use (RC 2001/83/EC)	Definitions, placing on the market, authorization procedure, manufacture and import, labelling and package leaflet
EU Delegated Regulation on safety features (Reg 2016/161)	Technical specifications, modalities of verification, characteristics of the database system and exemptions for safety features on the packaging of medicinal products for human use
EU Transparency Directive (RC 89/105/EVVG)	Procedural requirements, time limits and transparency for national decisions on reimbursement and pricing
Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use	EU-wide regulations on clinical trials with medicinal products for human use
Regulation (EC) No. 141/2000 On orphan medicinal products	Special rules for medicinal products for rare diseases
Regulation (EC) No. 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	Central authorization of medicinal products in the EU, establishment of the EMA
Summary of Product Characteristics Ordinance *Fachinformationsverordnung*	Structure of the summary of product characteristics
Ordinance on Distance Selling *Fernabsatz-VO*	Distribution of medicinal products by distance selling
Research Organization Act *Forschungsorganisationsgesetz (FOG)*	Promotion of science and research; framework conditions for data processing for the purpose of research and statistics; access to register data for company research
Instructions for Use Ordinance *Gebrauchsinformationsverordnung*	Development of the package leaflet
Health and Food Safety Act *Gesundheits- und Ernährungs-sicherheitsgesetz (GESG)*	Outsourcing of tasks and processes relating to medicinal products and medical devices from the Federal Ministry of Health to the AGES Medical Market Supervisory Authority
Therapeutic Products Authorization and Control Ordinance *Heilmittel-Bewilligungs und Kontroll-Verordnung*	Regulation on the principles of chief and control physician approval for therapeutic products, the subsequent control of prescriptions and the principles of documentation

Law	Regulatory areas
Labeling Ordinance *Kennzeichnungsverordnung*	Structure of the labeling/outer packaging
Hospitals and Health Resorts Act *Krankenanstalten- und Kuranstaltengesetz (KAKuG)*	Provisions on the establishment and operation of public and private hospitals and health resorts
NIS Ordinance	Obligation to notify each NIS before implementation (from 01.09.2010); includes creation, planning of NIS, testing, approval; provisions apply to pharmaceutical companies that create, test, approve, finance or on whose behalf an NIS is created and/or tested (repealed as of 07.10.2022)
Patent Act *Patentgesetz (PATG)*	Patent protection of medicinal products, among other things
Pharmacovigilance Ordinance Pharmakovigilanzverordnung	PV obligations of the marketing authorization holder, reporting of side effects and adverse events
Pharmaceutical Agents Ordinance Pharmareferentenverordnung	Authorization and examination of pharmaceutical representatives
Price Act *Preisgesetz*	Pricing and (through regulations) maximum mark-ups (margins)
Compulsory Prescription Act *Rezeptpflichtgesetz*	Compulsory prescription status
Directive 2001/83/EC Community code relating to medicinal products for human use	Regulations for commercially prepared medicinal products for human use that are placed on the market in the EU; affects a large part of the life cycle of a medicinal product; in Austria primarily implemented in the AMG.
Narcotic Drugs Ordinance *Suchtgiftverordnung (SV)*	Narcotic drug status, dispensing and placing on the market
Narcotic Drugs Act *Suchtmittelgesetzt (SMG)*	Narcotic drug status, dispensing and placing on the market
Rules of procedure for issuing the reimbursement code pursuant to § 351g ASVG (VO-EKO)	Regulation promulgated by the umbrella organization of Austrian social insurance institutions
Procedural Costs Ordinance pursuant to § 351g para. 4 ASVG (VK-VO)	Amount of the flat-rate reimbursement of costs for applications for proceedings in connection with the EKO

Law	Regulatory areas
Ordinance on ensuring the supply of medicinal products *Verordnung über die Sicherstellung der Arzneimittelversorgung*	Distribution restriction register of the BASG regarding prescription-only medicinal specialties in Austria; reporting obligations of marketing authorization holders; possibility of a parallel export ban..
Administrative Court Procedure Act *Verwaltungsgerichtsverfahrensgesetz (VwGVG)*	Procedural law before the Federal Administrative Court
Regulation (EU) 2021/2282 on health technology assessment	EU HTA Regulation - Health Technology Assessments at European level

Other regulations		Regulatory areas
Declaration of Helsinki Obligations of the doctor		Obligations of the doctor (e.g. in the case of clinical trials)
EU average prices according to ASVG		Regulation for the procedure of the price commission in determining the EU average price pursuant to S 351c para. 6 ASVG
Good Clinical Practices	GCP	Guidelines for clinical trials
Good Manufacturing Practices	GM/IP	Guidelines on the manufacture of medicinal products
Good Laboratory Practices	GLP	Guidelines on the investigation of medicinal products
Good Distribution Practices	GDP	Guidelines on pharmaceutical logistics
Good Pharmacovigilance Practices	GVP	Guidelines on pharmacovigilance
Principles of the Therapeutic Products Evaluation Committee	HEK	Information on the HEK with regard to economic evaluation criteria, pack sizes, subsequent control and principles for the verification of supply capability in the red area of the EKO
Guidelines on the Economic Prescribing of Therapeutic Products and Therapeutic Appliances	RöV	Guideline of the health insurance providers regarding the appropriateness and cost-effectiveness of prescriptions and the assumption of costs for medicinal products, formal requirements for prescriptions
Code of Conduct	CoC	Regulations for the information and advertising behaviour of pharmaceutical companies and cooperation with healthcare professionals and institutions as well as patient organizations

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13. Abbreviations

Abbreviations	Explanation | **A–C**
PPP	Pharmacy purchase price
AGES	Agency for Health and Food Safety
AMBO	Pharmaceutical Operating Regulations
AMG	Medicines Act
AMDC	Austrian Micro Data Center
AMVO	Austrian Medicines Verification Organization
AMVS	Austrian Medicines Verification System
ASVG	General Social Insurance Act
ATMP	Advanced Therapy Medicinal Products
AUVA	General Accident Insurance Institution
AVP	Pharmacy sales price
BASG	Federal Office for Safety in Health Care
BGBl.	Federal Law Gazette
GDP	Gross domestic product
BMGF	Federal Ministry of Health and Women's Affairs until 07.01.2018
BMSGPK	Federal Ministry of Social Affairs, Health, Care and ConsumerProtection
BVAEB	Insurance Institution for Public Employees, Railways and Mining
BVwG	Federal Administrative Court
c4c	Connect for Children
CAR-T cell therapy	Chimeric Antigen Receptor Cell Therapy
CHMP	Committee for Medicinal Products for Human Use of the EMA
COVID	Corona Virus Disease
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation

Abbreviations	Explanation | **D–H**
DAP	Custody account price (equivalent to FAP)
DCP	Decentralised procedure
DTP	Direct to Pharmacy
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHDS	European Health Data Space
EKO	Reimbursement Code
EMA	European Medicines Agency
Enpr-EMA	European Network of Paediatric Research at the European Medicines Agency
EMVO	European Medicines Verification Organisation
EUD	EU average price
R&D	Research & Development
TBE	Early summer meningoencephalitis
RTD	Full Time Equivalent
FAP	Factory Selling Price
FDA	U.S. Food and Drug Administration
g	Gram
GESG	Health and Food Safety Act
GMP	Good manufacturing practice (“gute Herstellungspraxis”)
GÖG	Gesundheit Österreich GmbH
GVP	Good pharmacovigilance practices
HEK	Therapeutic Products Evaluation Commission
HPV	Human papilloma virus
HTA	Health Technology Assessment

Abbreviations	Explanation | I–O
IGEPHA	Interest Group of Austrian Pharmaceutical Manufacturers and Depositors
IP	Intellectual property
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IPF	Institute of Pharmaceutical Economic Research
IQVIA	IQVIA Marktforschung GmbH
KFA	Health care institution
SMEs	Small and medium-sized enterprises
CIP	Box office sales price
LCI	Life-Course Immunization
LKF	Performance-based hospital financing
MAH	Marketing Authorisation Holder
millions, billions	million(s), billion(s)
mRNA	Messenger Ribonucleic Acid
MRP	Mutual recognition procedure
NAP.se	National Action Plan for Rare Diseases
NIH	U.S. National Institute of Health
NIS	Non-interventional studies
NKSE	National Coordination Office for Rare Diseases
OECD	Organization for Economic Cooperation and Development
ÖGK	Austrian Health Insurance Fund
OKIDS	Organization for Pediatric Drug Research
ÖVIH	Austrian Association of Vaccine Manufacturers
OTC	Over The Counter (Self-Medication)

Abbreviations	Explanation | **P–S**
PASS	Post-authorisation safety study
PedCRIN	Paediatric Clinical Research Infrastructure Network
PHAGO	Association of Austrian Pharmaceutical Wholesalers
PIC/S	Pharmaceutical Inspection Co-Operation Scheme
PIP	Paediatric Investigation Plan
Pkg.	Pack
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
PVA	Pension Insurance Institution
PVE	Primary Care Unit
QP	Qualified Person
RD	Rare Disease
RDP	Regulatory Data Protection
R&D	Research and Development
RSV	Human respiratory syncytial virus
SARS-CoV-2	Severe acute respiratory syndrome corona-virus type 2
SHA	System of Health Accounts
SMA	Spinal muscular atrophy
SPC	Supplementary Protection Certificate (Ergänzendes Schutzzertifikat)
Pcs.	Piece
SV	Umbrella organisation of social insurance institutions
SVS	Social Insurance Institution for the Self-Employed

Abbreviations	Explanation | **T–W**
Thousand.	Thousand
Vat.	Sales tax
VA	Insurance Institution
VHC	PHARMIG Code of Conduct
VO	Decree
VO-EKO	Rules of Procedure for the Publication of the Reimbursement Code pursuant to Section 351g ASVG
CPI	Consumer price index
WHO	World Health Organization

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