Facts & Figures

2026 Edition

PHARMIG

Association of the Austrian
Pharmaceutical Industry

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Imprint

Owned and Published by
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vektorama. grafik.design.strategie OG
Tuchlauben 8/11, 1010 Vienna

Print
Ferdinand Berger & Söhne GmbH
Wiener Straße 80, 3580 Horn

Currency
All values are given in euros. Total economic amounts are generally expressed in millions of euros, individual amounts and microeconomic indicators are generally expressed in euros.

Legal citations and technical terms
Quotations and technical terms are written between parentheses or with quotation marks.

202425021
PRINTED IN AUSTRIA

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PEFC
PEFC/06-39-01
www.pefc.at

Content

PHARMIG at a glance

PHARMIG – The Association of the Pharmaceutical Industry of Austria is a voluntary, politically independent organisation representing the interests of the pharmaceutical industry in Austria. PHARMIG represents about 120 companies with approx. 25,000 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 recognised 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!

Data and figures make it possible to substantiate and underpin facts. They help to put developments into context and to make well-founded decisions. This is of particular importance in the healthcare sector, especially as it is characterised by a high degree of complexity and is the subject of constant debate on how it can best be reformed.

With the current edition of our "Facts & Figures", we provide you with a concise overview of the Austrian healthcare system, the pharmaceutical industry and the supply of medicines. In doing so, we aim to strengthen the fact-based dialogue – between politics, management, research, industry, healthcare professions and the public.

New in this edition are current figures on the value-added effects of the pharmaceutical industry in Austria, with in-depth insights provided above all in Chapter 5 "Pharmaceutical Industry as an Economic Factor", which has been fundamentally restructured and expanded and now covers the areas of manufacturing, marketing and distribution as well as the overall economic impact of the sector.

Chapter 3.5 "Manufacturing and Quality Assurance" has also been reworked. In addition, Chapter 2 "Pharmaceutical Research" contains new content on the value added by clinical research in Austria.

The digital edition of Facts & Figures 2026 as well as selected graphics and the German version "Daten & Fakten 2026" 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 2026!

Kind regards

Mag. Alexander Herzog
Secretary General, PHARMIG

approx. 60.5 billion

euros were spent on healthcare in 2024

(equivalent to approx. 12.2 % of the national GDP)

75.8 % public

vs. 24.2 % private expenditure

1. Healthcare System in Austria

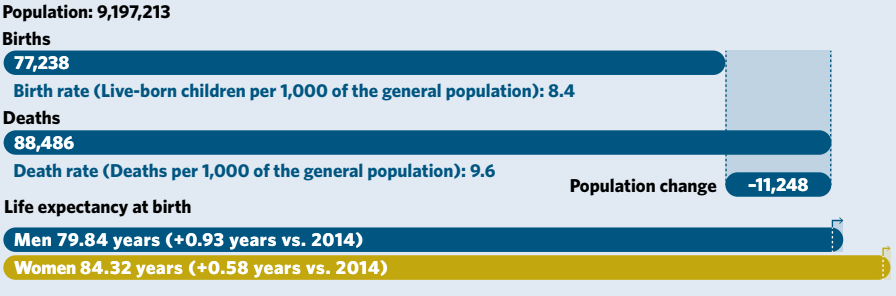
The Austrian healthcare system is characterised by the country's federalist structure. Due to the large number of decision-makers (federal, state, local, social security), the financing of healthcare is not centrally regulated and comes from various sources (such as taxes, social security contributions 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 2025 Austria's resident population numbered 9,197,213 people, 38,463 (+0.4 %) more than at the beginning of 2024. This increase in 2024 can again be traced back solely to immigration (1).

Demographic Indicators of Austria

Reporting year 2024



Source: STATISTIK AUSTRIA Demographie 2024 – Strukturen und Trends; Demographische Querschnittsindikatoren (2.3)

1.2 Social Expenditure

Social Indicators of Austria	2023	2024
Gross domestic product (GDP) in billion euros	477.8	494.1
Social spending in billion euros*	146.2	161.5
Social benefits in billion euros	142.0	157.7
of which: old-age benefits, in %	45.4	46.0
of which: sickness/healthcare, in %	28.1	27.6
Share of social benefits, in %	30.9	32.7

Source: STATISTIK AUSTRIA – Bruttoinlandsprodukt und Hauptaggregate, Sozialquote, Sozialausgaben und Finanzierung (4.5)

*Social spending: Sum of expenditure for social benefits, administrative spending and other expenditure (e.g. Interest)

In 2024, social spending in Austria amounted to 161.5 billion euros. Almost three quarters of this was spent on age-related and healthcare benefits. The increase in spending compared to 2023 (+10.5 %) is mainly due to above-average allocations to other social benefits in retirement (72.5 billion euros, +12.4 %) and to healthcare (43.6 billion euros, +9.4 %). The social ratio (share of social expenditure in nominal gross domestic product (GDP)) amounted to 32.7 % in 2024 and rose by 2.1 % compared to 2023 (5).

1.3 Health Expenditure

Health expenditure is made up of current health spending and investments in the health sector, according to the "System of Health Accounts" (6).

In 2024, total healthcare spending in Austria amounted to 60.5 billion euros, which corresponds to 12.2 % of the GDP. The ongoing health expenditure (without investments) is estimated at 57.8 billion euros in 2024. Compared to 2023, health expenditure increased nominally (at current prices) by 8.3 % and the GDP by 3.4 % (7,8).

Healthcare financing in billion euros	2024
Sum of healthcare expenditures	60.5
Ongoing health expenditures	57.8
Ongoing public health expenditures	43.8
Ongoing private health expenditures	14.0

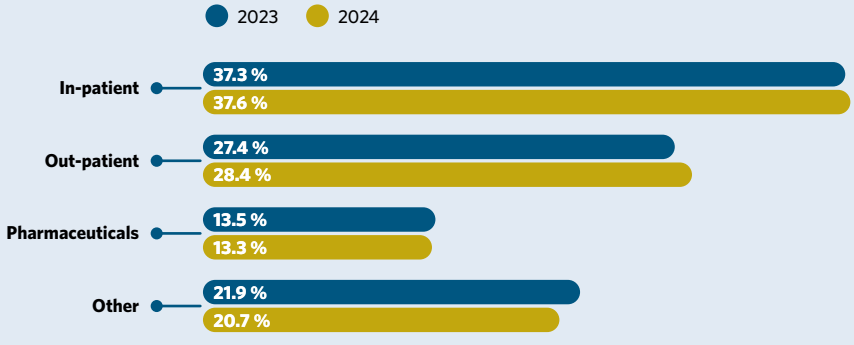
Source: STATISTIK AUSTRIA - Gesundheitsausgaben (79)

Broken down by public and private, more than three quarters of health expenditure is covered by public funds. Some areas recorded a notable increase: out-patient services in general, specialist and dental practices saw growth of 1.5 billion euros, or 12.8 %. Spending on home care services likewise rose by 11.8 %, and on patient transport and emergency services by 13.8 % (9).

With the share of current health expenditure of the GDP making up 11.7 %, Austria ranks fourth among 38 OECD countries (9):

- OECD-Average: 9.3 % 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 (17.2%), Germany (12.3%) and Switzerland (11.8%)

Healthcare spending by type



Source: Berechnet durch das Institut für Pharmaökonomische Forschung (IPF) unter Verwendung folgender Quellen: STATISTIK AUSTRIA, IQVIA (10)

The largest share (37.6 %) was spent on the in-patient sector in 2024, while 28.4 % was spent on the out-patient sector and 13.3 % on pharmaceuticals.

Spending on "Other" combines costs for long-term care, patient transport, public health services and prevention, management, medical devices and equipment as well as private insurance.

Compared to 2023, spending on in- and out-patient care increased in 2024, while spending for pharmaceuticals and costs for other areas fell (10).

Pharmaceutical expenditure includes consumption in pharmacy and hospital markets, including value-added tax (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).

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.

Ongoing health expenditures – Country comparison 2024 – in % of GDP[1]

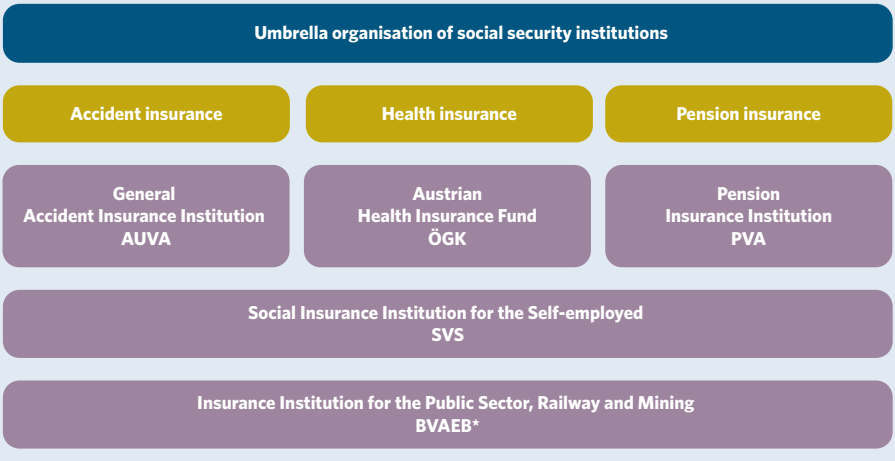
Timeframe	2014	2024
Germany	10.8	12.3*
Austria	10.5	11.8*
France	11.6	11.5*
Sweden	11.1	11.3*
Belgium	10.6	11.0**
Finland	9.8	10.6**
Portugal	9.3	10.2*
Netherlands	10.5	10.0*
Spain	9.2	9.2**
Italy	8.9	8.4*

[1] select OECD countries *preliminary value **approximated value

Source: OECD. Health expenditure and financing (11)

1.4 Social Security Structure

Structure of Austrian social security



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

Source: Österreichische Sozialversicherung, Auf Zukunftskurs – Sozialversicherung NEU (12)

The current structure of social insurance, consisting of five insurance institutions and the superordinate umbrella organisation, was introduced on 1 January 2020 (12).

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 7.6 million insured people (83 % of the Austrian resident population), the Austrian Health Insurance Fund (ÖGK) is the largest statutory health insurance fund in Austria (13).

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 Financial Management of Health Insurance Institutions

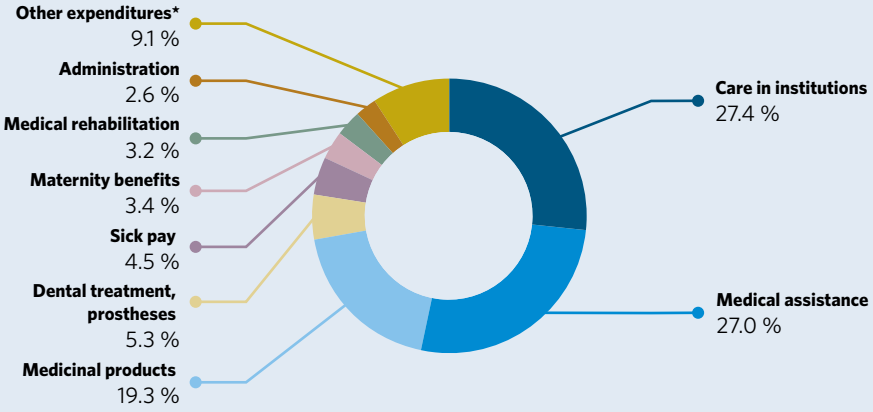
In 2025, the revenue of the statutory health insurance institutions amounted to about 28.8 billion euros, while expenditure amounted to 29.3 billion euros. Compared to 2024, this corresponds to an increase of 7.4 % and 6.5 %, respectively. The result amounted to negative 511 million euros (preliminary financial report 2025). In the 2025 annual average, there were 9,087,844 people eligible for benefits, 79 % of whom were contributors and 21 % were dependants (14).

In 2024 (preliminarily available data), health insurance institutions covered the costs of 109 million packages of pharmaceuticals and spent 4.7 billion euros (excluding VAT) on them. Each insured person accounted for an average of twelve packages and expenses of 516 euros (15).

The expense item Medicinal Products (gross) includes 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 institutions.

The sum of rebates increases every year.

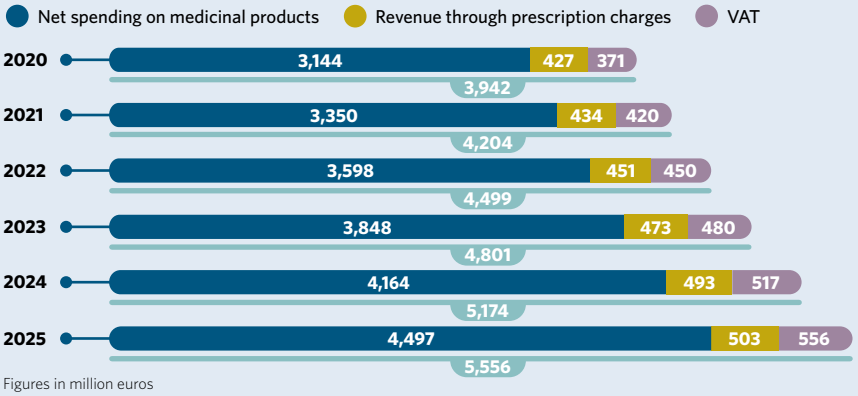
Spending of the health insurance institutions in 2025



Figures as a percentage of total revenue | Interim financial management 2025
*Incl. medical aids and appliances, home health care (nursing), rehabilitation benefits, health promotion and disease prevention, transport costs, etc.

Source: Die österreichische Sozialversicherung in Zahlen, März 2026 (14)

Spending on medicinal products

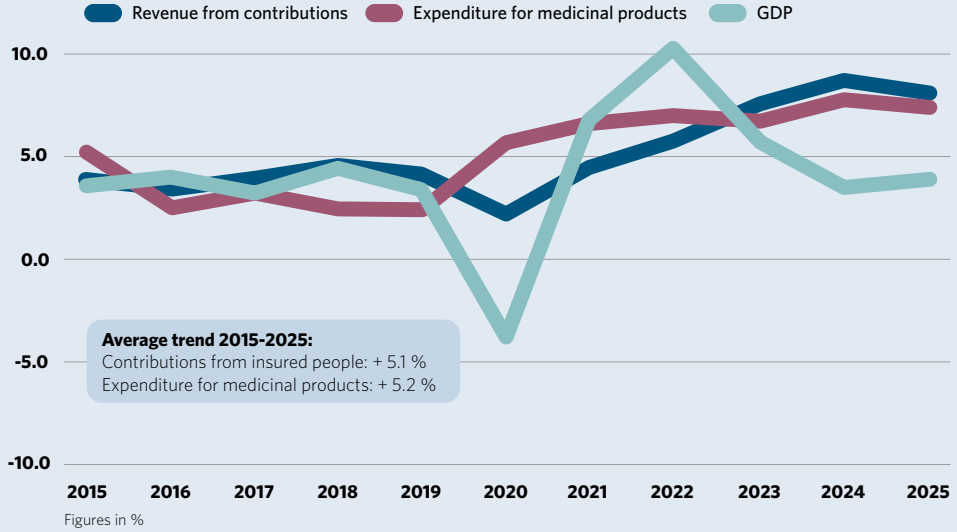


Figures in million euros

Source: Die österreichische Sozialversicherung in Zahlen, August 2025 und März 2026 (vorläufige Gebarung) (14;16)

The income of health insurance institutions from the contributions of all insured people increased by an average of 5.1 % per year from 2015 to 2025. Over the same period, expenditure on medicinal products increased by 5.2 % (excludes prescription fees collected and individual discounts and repayments from pharmaceutical companies) (14). During the period shown, GDP grew by an average of around 4.1% annually (17).

Change of revenue and cost for medicinal products 2015–2025



Figures in %

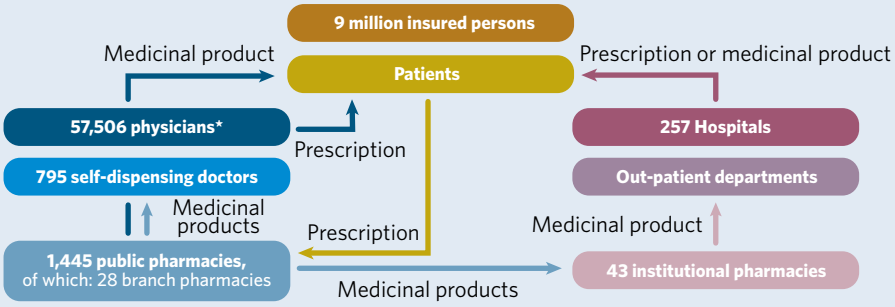
Source: STATISTIK AUSTRIA, Die österreichische Sozialversicherung in Zahlen, März 2026 (14;17)

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), **including self-dispensing**
- **Primary health care units** (PHCU) (currently 116 PHCU, of which 14 paediatric PHCUs) (18)
- **Hospitals and hospital out-patient clinics**
- **Public pharmacies**
- **Other medical/therapeutic services**

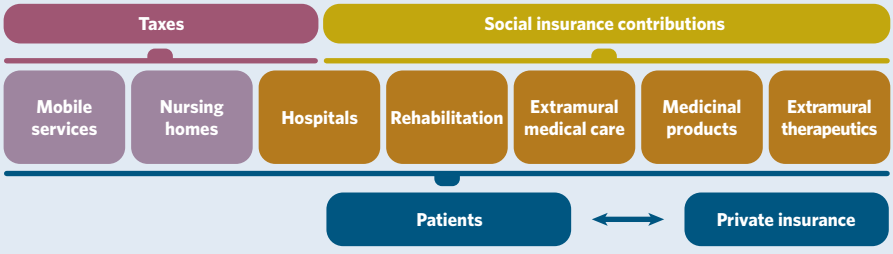
Structure of Austria's healthcare system 2024



*including dentists

Source: STATISTIK AUSTRIA – Einrichtungen und Personal im Gesundheitswesen, Ärztekammer Österreich, Österreichische Apothekerkammer (19–21)

Healthcare financing



Source: Das österreichische Gesundheitssystem Zahlen - Daten - Fakten (22)

Financial Equalisation

Financial equalisation 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 equalisation system. Financial equalisation is an agreement that must be negotiated and adopted by mutual agreement between the federal government, the federal states, and the municipalities. With the conclusion of a financial equalisation agreement, the tasks that each party must 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 equalisation scheme that will apply from 2024 to 2028. In the area of health, it will provide additional funds, in particular, to strengthen the established physician sector, the hospital out-patient sector, digitalisation, and eHealth, as well as health promotion and vaccination (23).

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, organisation, and financing of healthcare.

To this end, the federal and state governments and the social insurance conclude corresponding agreements in accordance with article 15a B-VG on target management for health and on the organisation 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 (24,25).

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 specialised medicinal products, the centrepiece 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 (26).

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 in particular to the assessment of the additional medical-therapeutic benefit compared to the comparator therapy in conjunction with cost-effectiveness, to its use or non-use, to certain criteria for use, or to accompanying measures associated with such use (e.g. the establishment and population 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 standardised 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 (27).

Furthermore, 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 (28).

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 (29). 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 (30).

The evaluation board took up its work in autumn 2024. By January 2026, six evaluations had been carried out (31). The government programme 2025–2029 provides for appropriate "scientific and transparent monitoring of the implementation of the evaluation board and its impact on timely care".

Pharmaceuticals for Joint Financing

The assignment of medical services between the extra- and intramural sectors is, strictly speaking, clearly regulated by law. Nevertheless, against the backdrop of the development of new innovative therapies, payer institutions for pharmaceuticals at the interface or in the transition from the intra- to the extramural sector have an increased interest in joint financing through cost sharing in a specific ratio. This current development is specifically reflected in agreements for "Medicinal products for Joint Financing" (MedGeF) or a specific process for the affected pharmaceuticals (32).

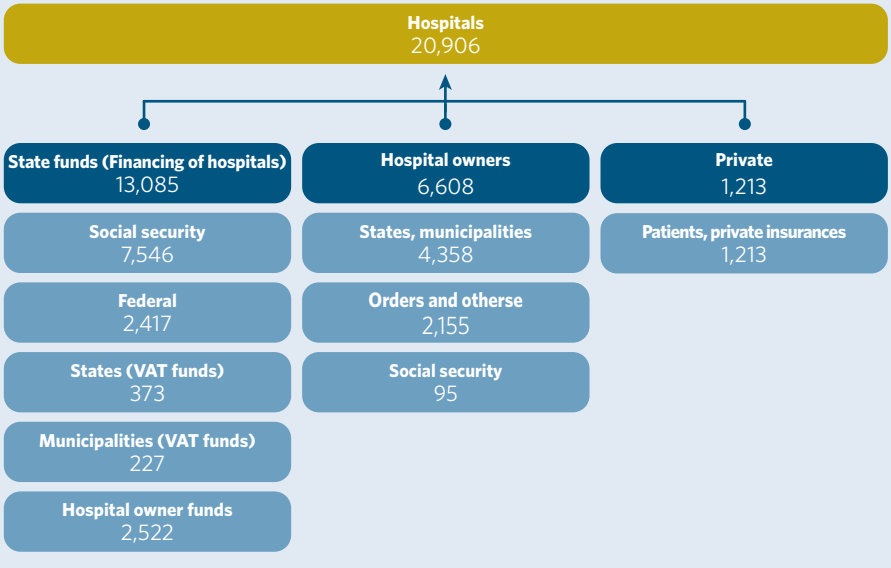
In this context, agreements are concluded between the umbrella organisation of social insurance institutions and the respective hospital operator, which provide for cost sharing for such pharmaceuticals in a specific ratio (33).

This novel instrument is intended as a more targeted financing of medicines in this interface area. It remains to be seen to what extent this will facilitate and expedite patients' access to treatment, rather than introducing an additional bureaucratic process involving lengthy coordination procedures (32).

1.7 Financing of Healthcare Institutions

The expenditure of Austrian hospitals that bill according to the LKF scheme (performance-oriented hospital financing) amounted to 20.9 billion euros in 2024. 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 2024



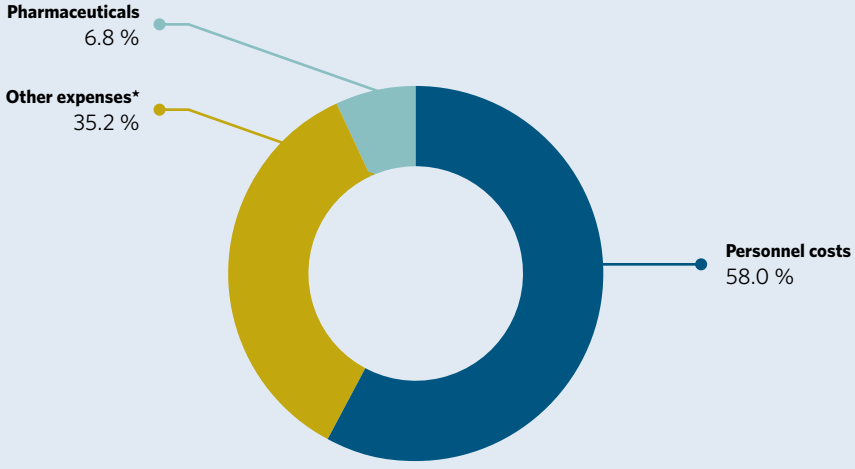
Figures in million euros

Source: Berechnet durch das Institut für Pharmaökonomische Forschung (IPF) unter Verwendung folgender Quellen: Bundesrechnungsabschluss 2024, Krankenanstalten in Zahlen 2024, Statistik Austria SHA, eigene Berechnungen (35)

State-funded Hospitals

The total cost of hospitals, that are financed by state health funds (105 hospitals with 39,888 beds), amounts to 20.9 billion euros in 2024 (34,36). Social insurance paid for a significant portion of the total cost. Of 13 billion euros, which were contributed by the state funds, around 60 % was paid by social insurance (35). These costs relate to in-patient and out-patient care. 58 % of these costs are attributable to personnel costs, while approximately 7 % are attributable to pharmaceuticals and 35 % to other expenses (34).

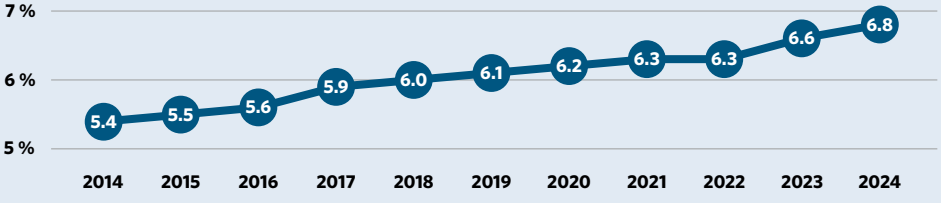
Expenditure in hospitals 2024



*Catering, training, etc

Source: BMASGPK - Kosten der landesgesundheitsfondsfinanzierten Krankenanstalten (34)

Share of medication costs in total costs 2014–2024



Figures in %

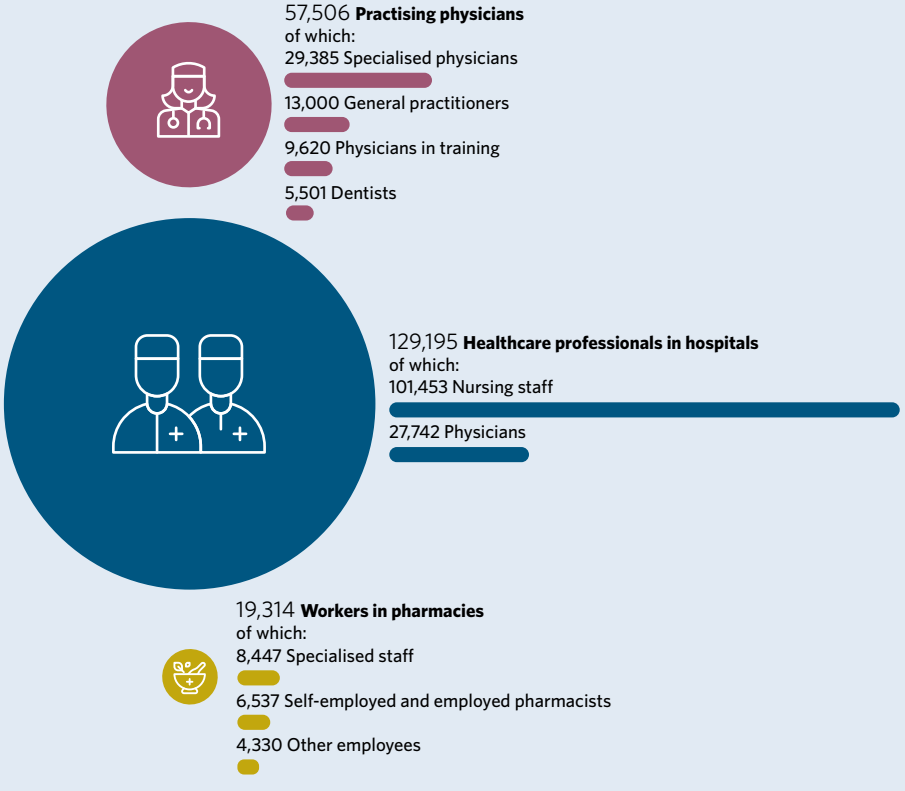
Source: BMASGPK - Kosten der landesgesundheitsfondsfinanzierten Krankenanstalten (34)

The share of pharmaceutical spending of total spending in hospitals has risen only slightly in the last ten years.

1.8 Healthcare Workers

At the end of 2025, there were 1,445 public pharmacies (with 28 branch pharmacies), 43 hospital pharmacies and 795 self-dispensing doctors in Austria. These provided 9.2 million people with medicinal products (19,21).

Healthcare workers 2024



Source: STATISTIK AUSTRIA – Einrichtungen und Personal im Gesundheitswesen; Österreichische Apothekerkammer (20,21)

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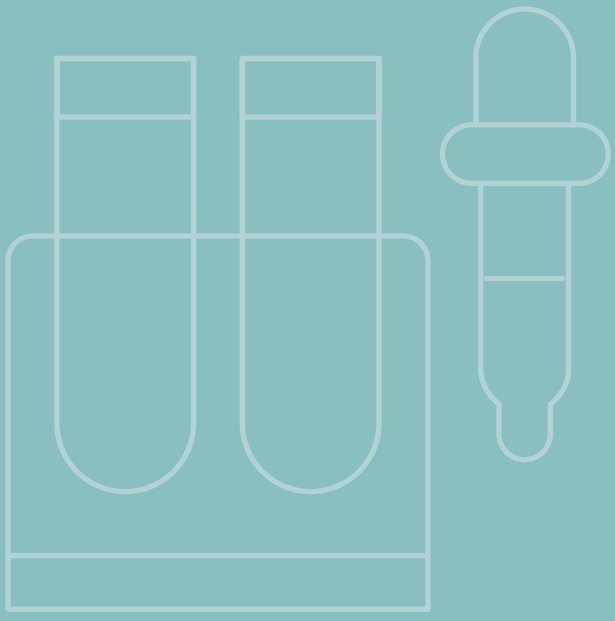
241 clinical trials

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

Research quota in 2025

3.39 %



2. Pharmaceutical Research

2.1 Austria as a Research Location

In the comparative assessment of research and innovation performance of the EU member states for the years 2018–2025, Austria ranks eighth. The "European Innovation Scoreboard", which is published annually by the European Commission, has again classified Austria as a "Strong Innovator" in 2025. Compared to 2018, Austria has shown a significant improvement of +8.2% with a performance of 128.3% compared to the EU average in 2025. This puts Austria, together with Ireland, Belgium, Luxembourg and other strong innovators (such as Germany, France and Estonia) above the EU average in terms of innovation performance. Sweden, Denmark, the Netherlands and Finland are classified as innovation leaders, with performances well above the EU average (37).

The share of expenditures for research and development (R&D) in the nominal Gross Domestic Product (GDP) is expressed as the **research quota,** as a percentage. For 2025, Statistik Austria currently estimates this at 3.39% for Austria (38). This places the country among the top 3 in the EU, exceeding the European target value of 3% for the eleventh consecutive time (39, 40).

For 2024, the estimated research quota was 3.24 %. In a comparison of EU countries from 2024, Austria has the third-highest research quota, after Sweden (3.56%) and Belgium (3.36 %) (40).

According to an estimate by Statistik Austria, 17.6 billion euros will be spent on research and development (R&D) in 2026 in Austria (40):

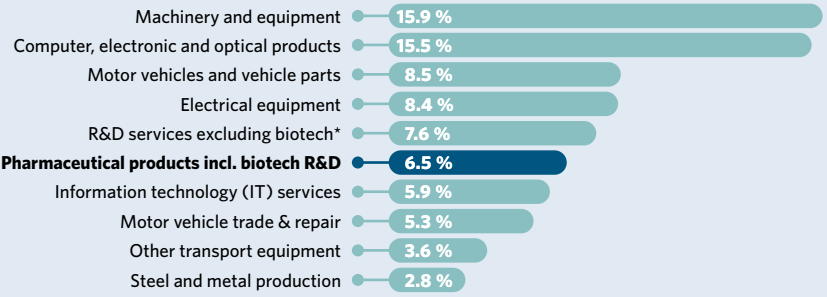
- **Companies account for the largest share of total research expenditure at 50 % or 8.9 billion euros.**
- **33 % is covered by the public sector (5.8 billion euros) and**
- **16 % from abroad (2.9 billion euros).**

In 2023, 6.5 % of total corporate research and development spending in Austria was attributable to companies in the life sciences sector (pharmaceutical companies and companies engaged in the research and development of biotechnology).

Among the 32 industry groups analysed, these companies rank sixth. This corresponds to a volume of approximately 725 million euros for the pharmaceutical industry out of the total of 10.6 billion euros in R&D spending (41).

Top 10 industry groups by total corporate R&D spending

A total of 32 industry groups could be analysed: the top 10 industry groups account for 80 % of total corporate R&D spending.



*This category comprises R&D services in the natural sciences, engineering, agricultural and medical sciences, as well as in law, economics, social sciences, linguistics, cultural studies and the arts.

Source: ECO Austria – Wertschöpfungswirkungen der pharmazeutischen Industrie in Österreich (41)

2.2 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 1 February 2025, new applications must be submitted and approved in accordance with **EU regulation 536/2014 (42) on clinical trials on medicinal products for human use (CTR)** to the purpose-built centrally set up **Clinical Trials Information System (CTIS).** A three-year transitional period made it possible to convert clinical trials that had been submitted according to regulation 2001/20/EC and had not been completed before 31 January 2025, to the requirements according to regulation 536/2014.

Additional to the EU regulation 536/2014, national requirements are regulated in the Austrian Medicinal Products Act (AMG) in § 2a and from § 28 to § 48. An overview of these legal requirements and recommendations is summarised on the BASG website and the platform of the CTR Ethics Committees (43,44).

Preclinical Studies

Before an active substance 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 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 substance in vivo. However, meaningful proof of efficacy is not always possible and therefore not mandatory. Only when an active substance 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 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.

Sequence of the Individual Clinical Phases

The relevant information on the marketing authorisation of a medicinal product is collected in the clinical trials of phases I to IIIa (45). Further studies that are carried out after submission for marketing authorisation or after authorisation (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 substance is used for the first time to determine its behaviour 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 substance 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.

To minimise the risks for study participants, especially in phase I studies, the European Medicines Agency (EMA) has published separate guidelines (46). 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 effects are 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 number of 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 substance or the control substance is being administered). This is to avoid a possible influence on the treatment result.

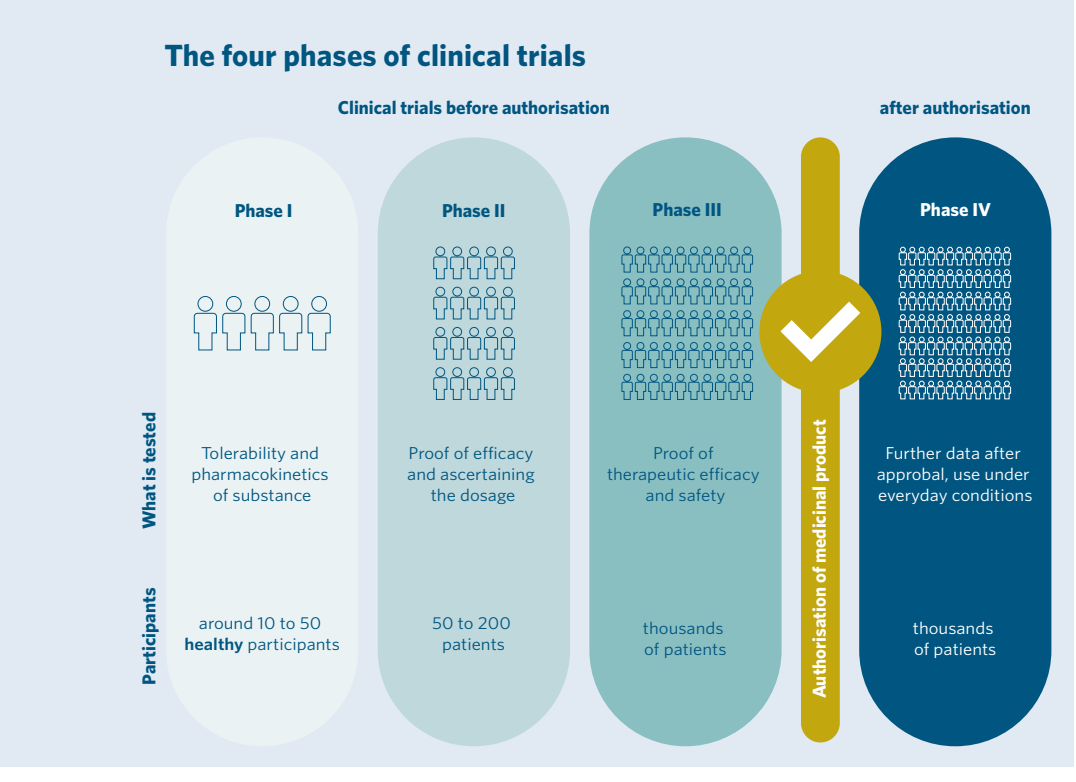
Phase III: Proof of Therapeutic Efficacy

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 adverse reactions.

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 multicentre 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 trials, 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 authorisation of the active substance can be submitted to the appropriate authorities.

Phase IV: Post-Authorisation 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.



Source: adaptiert nach BASG Klinische Studien (45)

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 31 January, 2022, NIS are defined as "clinical studies that are not clinical trials". The NIS are particularly suitable for proving the efficacy of a speciality medicinal product under practical conditions and for documenting adverse reactions that were not recorded in the clinical trial programme due to the limited number of cases. The boundary to clinical trials must not be crossed.

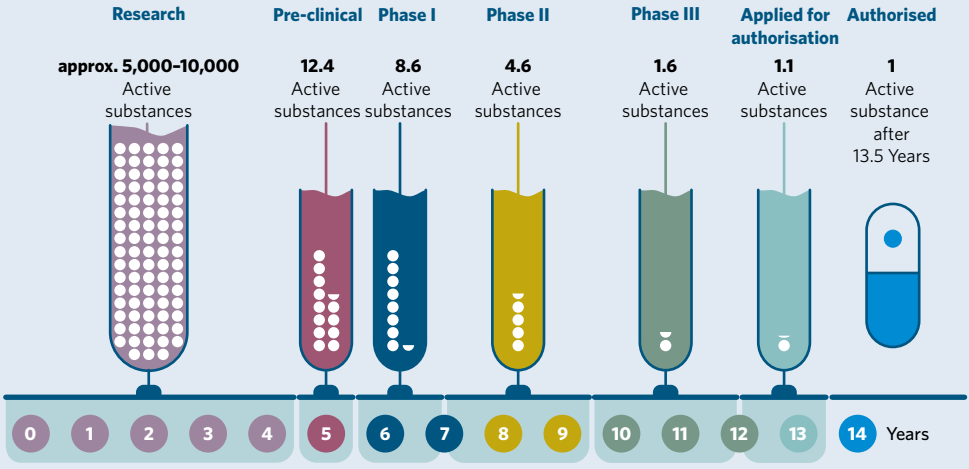
The decision to prescribe the medicine must not be taken at the same time as the decision to include the study participants in the non-intervention study. Furthermore, no diagnostic or monitoring procedures may be used that go beyond normal clinical practice. This is to ensure that the treatment corresponds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

In this regard, the Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection (BMASGPK) and the Federal Office for Safety in Health Care (BASG) published a guideline in 2022 to help differentiate those from other studies and the "PHARMIG Guideline on the Quality and Transparency of Non-Interventional Studies" has also been updated:

- BMASGPK and BASG Guidelines for the Distinction between Clinical Trial – Non-Interventional Study – Other studies (47)
- PHARMIG Guideline on Quality and Transparency of Non-Interventional Studies (48)

There is no longer an obligation to report NIS. (The previous ordinance on the reporting obligation for NIS was repealed on 7 October 2022.)

Developmental stages of a medicinal product



Source: Paul, S. M. et al.: Nature Reviews Drug Discovery 9, 203-214 (2010) (49)

Clinical Trials in Austria – A Statistical Overview

Since the Clinical Trials Regulation (CTR) came into effect in January 2022, there has been a significant decline in initial applications for clinical trials in Austria – from 285 (2021) to 205 (2024). This continues a European trend that is primarily caused by the increased regulatory, administrative and technical requirements in the Clinical Trials Information System (CTIS). In 2025, the situation stabilised at a low level, with 226 initial applications (43). A significant share of these applications (7), however, are resubmissions of withdrawn or rejected studies rather than new projects.

Both commercial and academic sponsors are affected, with the decline being more pronounced in the academic sector. In particular, there has been a significant decline in Phase I and Phase II trials in Austria – a decrease of almost 50 % from 2021 to 2025. Phase III trials remain stable, especially in the commercial sector.

In addition to the Europe-wide effects, additional national requirements and fee structures as well as other structural hurdles such as lengthy contract negotiations or limited financial and human resources are having a dampening effect on submission behaviour in Austria.

Targeted location initiatives – such as accelerated procedures or harmonisation for combination studies, medicinal products and medical devices – are important steps that have been introduced to reposition Austria specifically for early study phases.

Since 2022, Austria has chaired the Clinical Trials Coordination Group (CTCG) – the central European working group for the operational implementation of the CTR. The CTCG coordinates assessments, develops guidelines and promotes harmonisation between member states.

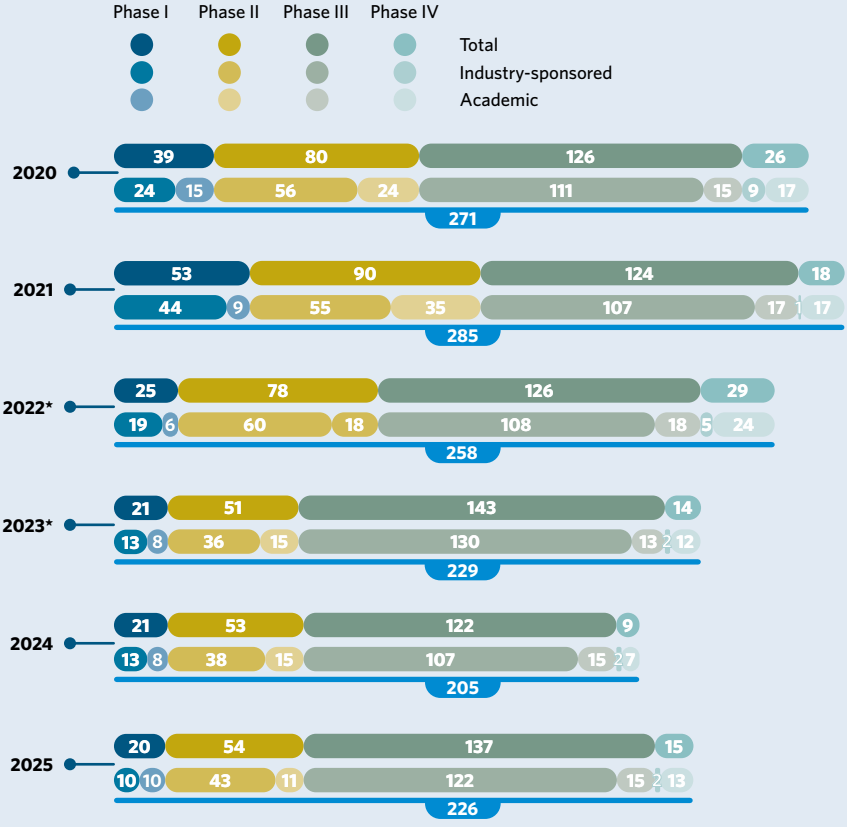
Under the Austrian chairmanship, key documents were published in 2023 – including explanations on amendments requiring approval, safety processes and requirements for combination studies.

With FAST-EU ("Facilitating and accelerating clinical trial assessment in the EU"), Austria is now also playing a significant part, at European level, in shaping one of the currently most important location initiatives in the field of clinical trials. At its core is a maximum overall procedure of 70 calendar days from submission in CTIS to completion of the procedure. This is made possible above all by parallelised validation and assessment processes and a strengthened role for the reporting member state.

This work not only strengthens the European framework but also underlines Austria's active contribution to the further development of the regulatory system.

For sponsors, this provides clear guidelines, greater predictability and early involvement, and for Austria as a whole, influence, visibility and expertise.

Number of clinical trials requested for medicinal products by phase in Austria



Absolute figures

*Due to an incorrect presentation of transitions and procedures without the participation of Austria between CTIS and the national system, the years 2022 and 2023 had to be re-evaluated. After adjustment, the total figures are significantly lower than originally stated..

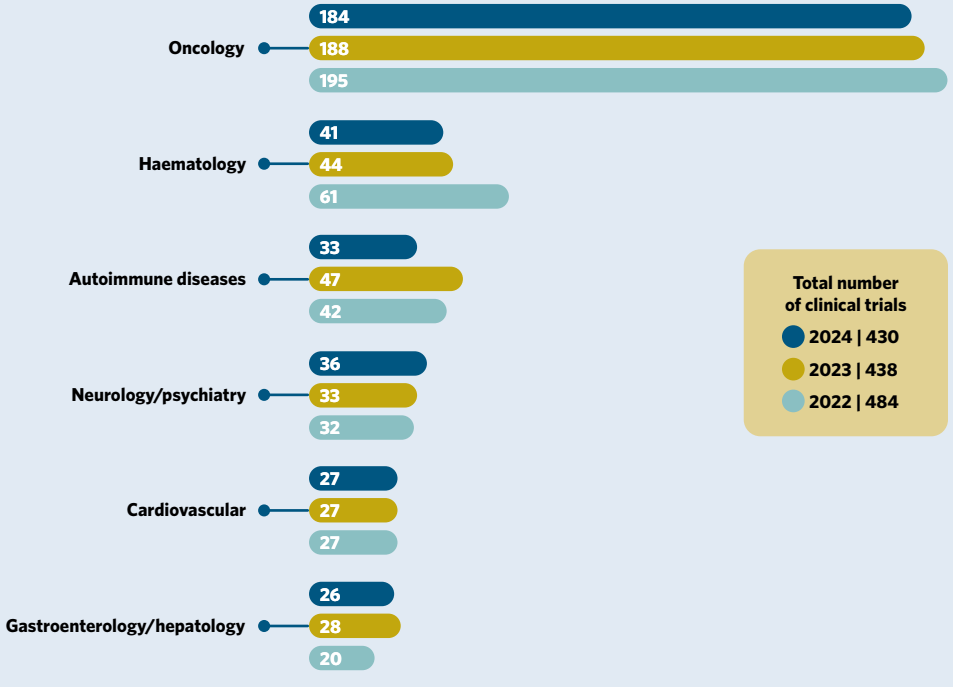
Source: BASG Klinische Prüfungen von Arzneimitteln (43)

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. From 2022 to 2024, around 31 companies took part in the survey. This corresponds to a market coverage of approx. 77 % (measured by the revenues of all PHARMIG member companies) (50).

Number of clinical trials 2022–2024 broken down by the most researched indications

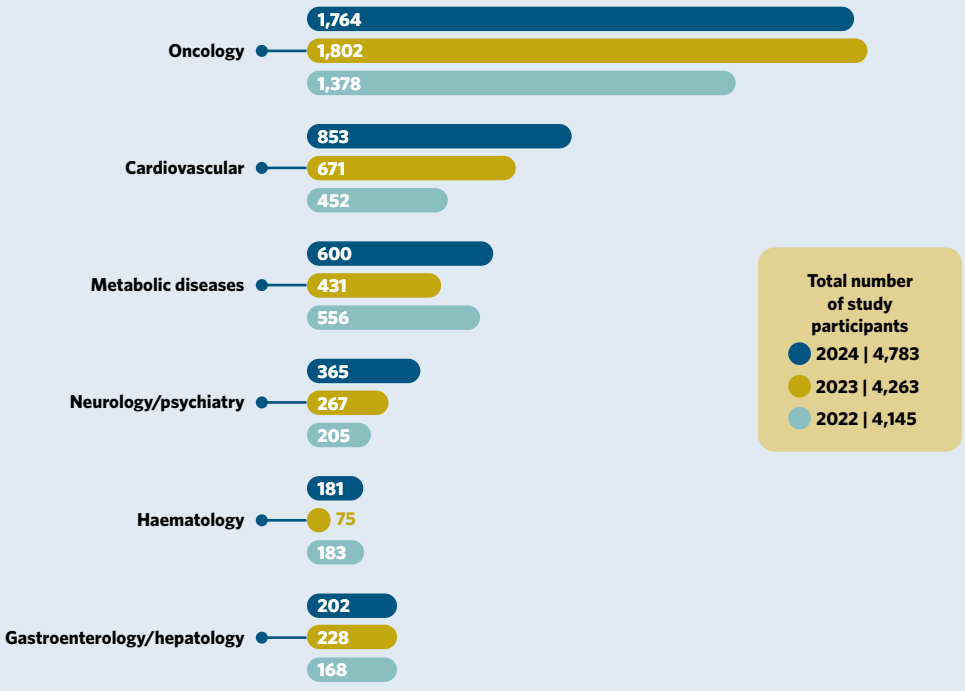


Absolute figures

Source: PHARMIG – Umfrage zu industrie-gesponserter klinischer Forschung in Österreich (2022–2024) (50)

The **average sum** of approx. **451 clinical trials** per year in the years 2021–2024 includes ongoing, started and completed clinical trials (50).

Number of study participants in clinical trials broken down by indication with the highest average number of participants



Angaben in Absolut

Source: PHARMIG – Umfrage zu industrie-gesponserter klinischer Forschung in Österreich (2022-2024) (50)

On average, around 4,397 study participants have taken part in clinical trials in Austria between 2022 and 2024. Information on the number of trial participants is provided for an average of 85 % of all clinical trials (50).

Number of ongoing clinical trials by phase in Austria 2022–2024

Absolute figures

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2022–2024) (50)

Additionally, the support of the pharmaceutical industry enabled an average of 90 "Investigator Initiated Trials", meaning academically funded research projects, per year in 2022–2024 (50).

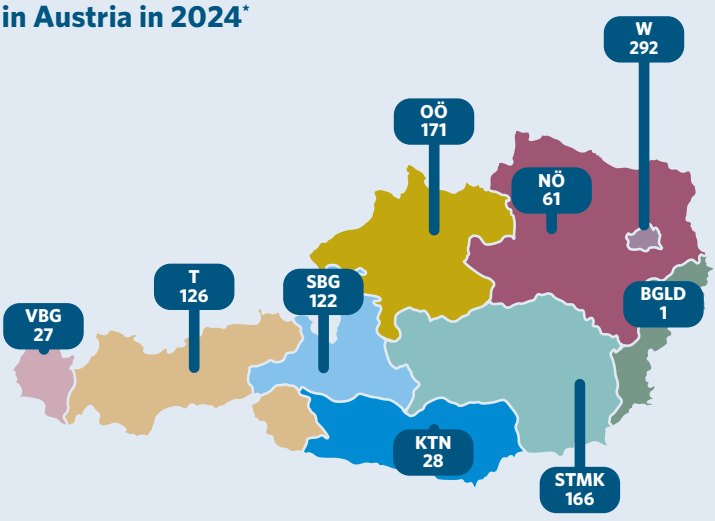
Distribution of study participants in ongoing clinical trials by phase in Austria 2022–2024

Absolute figures

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2022–2024) (50)

Information on the number of study participants was provided for an average of 85 % of clinical trials.

Distribution of ongoing clinical trials per state in Austria in 2024*



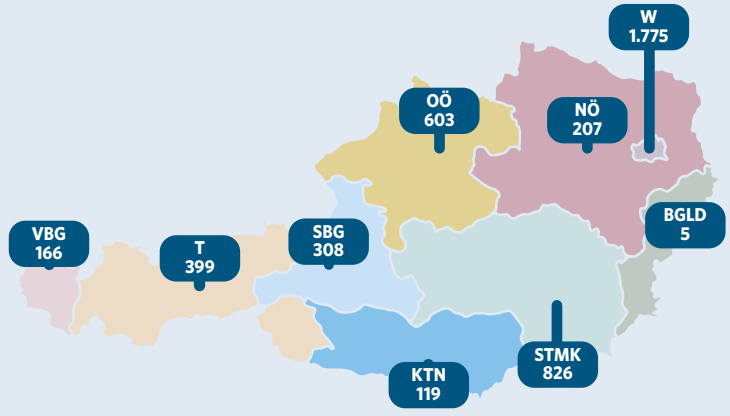
*Data on 89% of the clinical trials. | Absolute figures
Most ongoing clinical trials in Austria are multinational and multicentre, i.e. a clinical trial can run in two or more federal states or centres

Source: PHARMIG - Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2022-2024) (50)

	W	NÖ	OÖ	STMK	T	KTN	SBG	VBG	BGLD
Number of inhabitants Absolute figures	2,038,514	1,730,270	1,538,341	1,272,742	778,730	570,104	573,749	412,273	301,736
	22.12 %	18.77 %	16.69 %	13.81 %	8.45 %	6.19 %	6.23 %	4.47 %	3.27 %

Source: STATISTIK AUSTRIA - Bevölkerung zu Jahres-/Quartalsanfang (1)

Average number of study participants in ongoing clinical trials per state in Austria in 2024*



*Information on the number of patients and federal state distribution for 85 % of clinical trials. | Absolute figures

Source: PHARMIG - Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2022-2024) (50)

Paediatric Pharmaceutical Research

50–90 % of the medicinal products commonly used in paediatrics are not authorised for children because children and adolescents have long been excluded from clinical research due to ethical concerns and legal frameworks. However, an adequate supply of medicinal products that have been tested and authorised specifically for children is necessary and has therefore been required by EU regulations since 2007 (51).

A Paediatric Investigation Plan (PIP) must be implemented for all new authorisations, indications, dosages or changes in the method of administration of a medicinal product that has already been authorised. This requires medicinal product studies with children and adolescents (52).

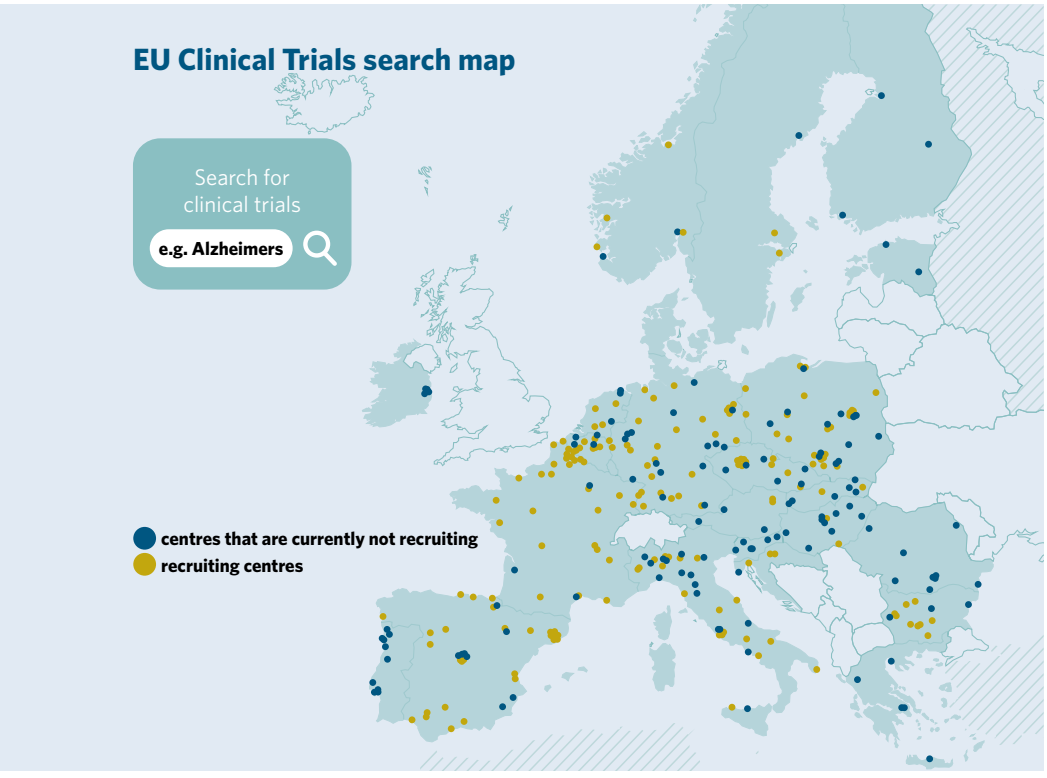
Transparency of Study Data

Worldwide register

- Since 2000, the U.S. National Institutes of Health (NIH) has maintained the largest public register, **ClinicalTrials.gov.** It publishes clinical trial data from all 50 US states and a further 200 countries (53).

Registers in the EU

- Clinical trial data from the EU, Iceland, Liechtenstein and Norway before 31 January 2022 are accessible in the **Clinical Trials Register** operated by the European Medicines Agency (EMA) (clinicaltrialsregister.eu). The data is based on clinical trials conducted in accordance with EU Directive 2001/20/EC (54).
- Data on clinical trials conducted in the EU, Iceland, Liechtenstein and Norway since Jan. 31, 2022 in accordance with the EU Regulation on clinical trials on medicinal products for human use (Regulation (EU) No. 536/2014) are published by the EMA in the **EU Clinical Trials Register** (euclinicaltrials.eu). The essential information on these clinical trials can also be accessed via a map search function that is easy to understand for laypersons (55).
- A post-authorisation safety study (PASS) is a study carried out after a medicinal product has been authorised, 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 (56). The EMA publishes the protocols, abstracts, and final reports of PASS studies in the **HMA-EMA Catalogues of real-world data sources and studies** (formerly EU register of Post-Authorisation Studies (EU PAS Register)) (57).



Source: eigene Gestaltung nach EMA Clinical Trials Search (55)

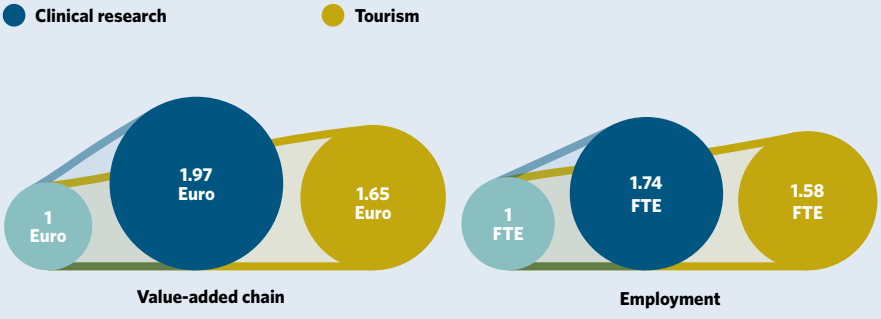
The Value Creation of Industry-Sponsored Clinical Trials

The conduct of clinical trials by the pharmaceutical industry creates – in addition to the benefits for patients – positive macroeconomic effects. These extend far into the economy and society and contribute to cost savings in the healthcare system.

An updated analysis for the period 2020–2024 shows that this generated added value of 174 million euros per year. Each year, a medical treatment value of 122.3 million euros was funded through 463 industry-sponsored clinical trials, with an average value of medical treatment of 37,989 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 0.21 % of current annual health expenditure (180).

Adjusted for inflation, the annual treatment value of the medical services funded by clinical trials is below the level of the 2012–2017 analysis (58). The treatment value of 100 million euros in 2018 would correspond to purchasing power of around 135 million euros in 2025. The main reasons for the lower level are, in particular, the decline in clinical trials of almost 30 % recorded since 2021 and the lower number of participating patients.

Industry-sponsored clinical trials



Source: Walter, E. et al (2026). Tracking economic change over a decade: an analysis of Austria's industry-sponsored clinical trial landscape and implications for policy. Journal of Medical Economics, 29(1), 167-1631. (180)

Every euro invested by the pharmaceutical industry in clinical trials generates 1.97 euros for the Austrian economy. Jobs in the order of 2,276 full-time equivalents (FTE) are created and secured, resulting in an employment multiplier of 1.74 (180). This means that both the value-added multiplier and the employment multiplier exceed those of the tourism sector – unlike in the 2012–2017 period (58).

The overall economic benefit of 174 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.

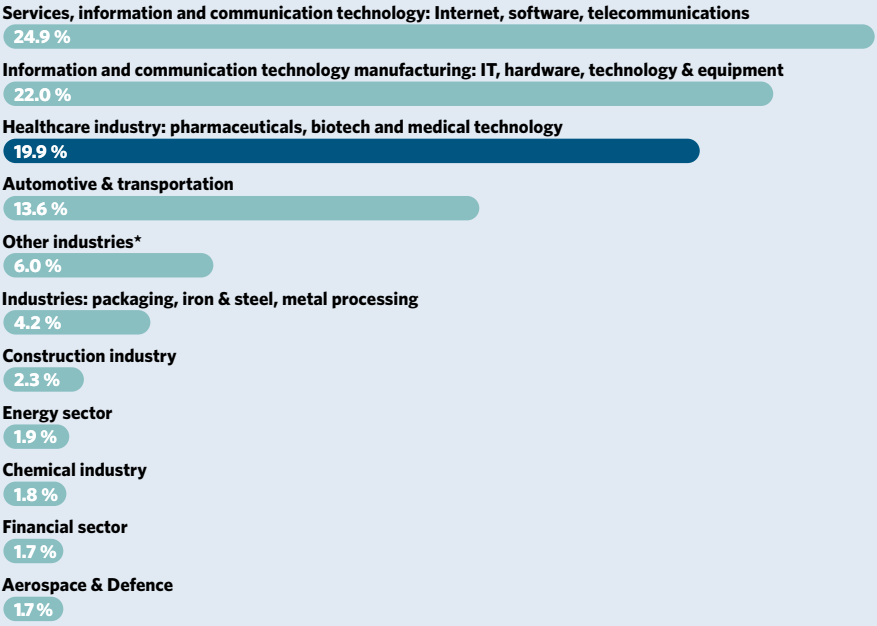
Effects	Added value	Employment
Direct effects	88.24 million Euros	1,311 FTEs
Indirect effects	48.30 million Euros	596 FTEs
Secondary effects	37.51 million Euros	368 FTEs
Total effects	**174.05 million Euros**	**2,276 FTEs**
Multiplier	1.97	1.74

Source: Walter, E. et al (2026). Tracking economic change over a decade: an analysis of Austria's industry-sponsored clinical trial landscape and implications for policy. Journal of Medical Economics, 29(1), 167-1631. (180)

2.3 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) 2024



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

Source: Europäische Kommission - The 2025 EU Industrial R&D Investment Scoreboard (59)

In research and development, the "healthcare industry" (pharmaceutical, biotech, and medical technology industry) ranks third behind the information and communication technology sector: 287 billion euros were invested in research and development in 2024 (59).

2.4 Special Challenge – Antibiotics Development

Antimicrobial resistance (AMR) causes 35,000 deaths per year in the European Economic Area (EEA) alone. According to estimates by the Organisation for Economic Co-operation and Development (OECD), AMR costs the EU/EEA countries almost 11.7 billion euros per year through higher healthcare expenditure and reduced labour productivity. Between 2025 and 2050, an estimated 39 million deaths are expected to be directly attributable to bacterial AMR (60).

In this light, the development of new antimicrobial agents in the fight against AMR is of crucial importance and at the same time a massive challenge. Incentives to invest in the research and development of antibiotics are currently insufficient. Antibiotics should be used sparingly in order to maintain their effectiveness and slow down the emergence of resistances. Although this is imperative from a stewardship perspective, this factor limits sales volumes and it is not possible to refinance the costs of research and development (R&D). The R&D pipeline for antimicrobials is inadequate and significantly underfunded due to scientific and economic challenges (61,62).

- Between 2017 and 2023, only ten new antibiotics and combinations were authorised, of which only two were categorised as innovative by the WHO.
- None of these form a new class of antibiotics.
- Of the four bacterial pathogens categorised as critical by the WHO, only one antibiotic candidate is currently in phase III clinical trials.
- Only two of the seven high-priority pathogens have innovative antibiotic candidates in development, and for five of them three or fewer candidates are at some stage of clinical development (63).

Longer-term political measures are required to counteract the loss of experienced antibiotics researchers to other disease areas, to create incentives for further investment in the development of new antibiotics and to sustainably revitalise the R&D pipeline in this area.

2.5 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.

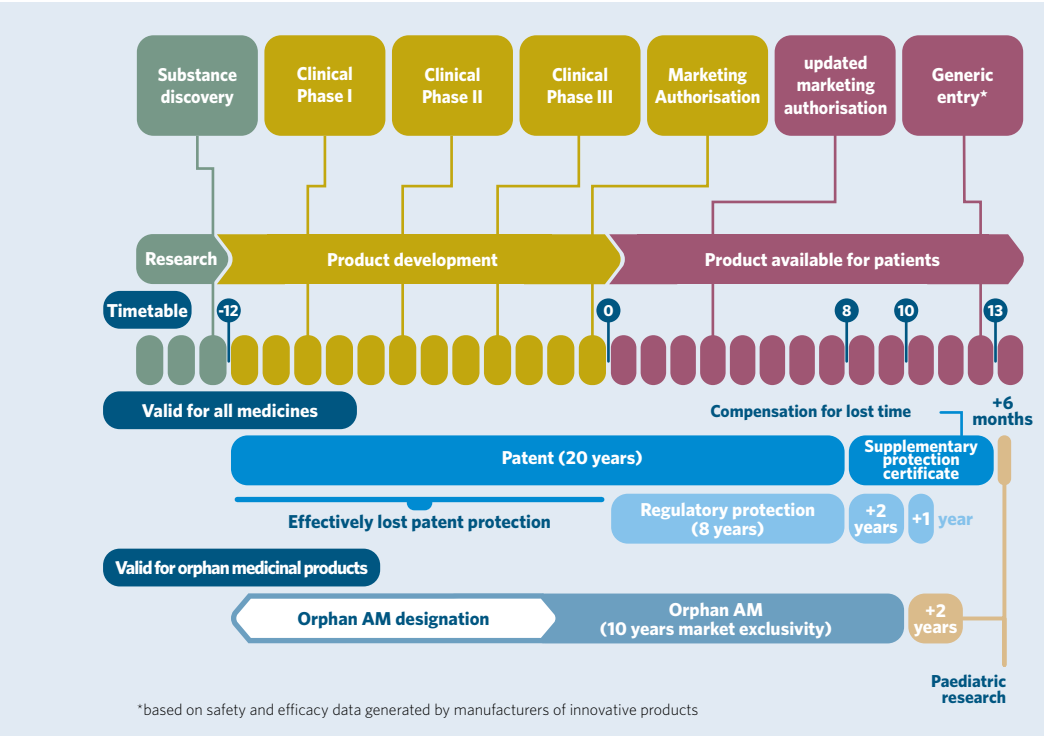
The protection of intellectual property is the best incentive for investment in research and development.

Innovative medicinal products (like all other goods) have a patent 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 authorised as a speciality medicinal product (see Section 2.2 and Chapter 3) This results in an actual patent's useful life of only about eight years on average (64).

In 2023, the pharmaceutical industry filed 12,425 patent applications with the World Intellectual Property Organization (WIPO) (64).

The effective patent life is eight years, on average.

Once the last form of intellectual property protection (e.g. patent, Regulatory Data Protection (RDP), Supplementary Protection Certificate (SPC)) has expired, other companies may manufacture and market medicinal products with the same active substance (generics) or with similar active substances (biosimilars) (see Section 3.2). As a result, original preparation can usually no longer contribute to the refinancing of research and development costs after the expiry of the corresponding IP rights.



Source: IQVIA, PHARMIG

Apart from patent protection, there are other different forms of intellectual property.

The table below gives an overview of these and their historical purposes (64):

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. Unique feature of the patent: To obtain protection, the invention must be disclosed when the patent application is filed so that others have access to new knowledge.

Details

- 20 years from the filing date
- Publication of the details of the invention 18 months after filing
- Types of inventions: Active substances, processes, application, improvement, formulation, device
- Criteria for patentability: novel, not obvious, useful
- Enforcement by patent holder

Type of IP: Supplementary Protection Certificate (SPC)

Historical Purpose

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

Details

- Maximum duration of 5 years
- Maximum total exclusivity of 15 years from authorisation (MA)
- Only for products with an authorisation
- Only one SPC per product (i.e. either active substance or combination thereof)

Type of IP: Regulatory Data Protection (RDP)

Historical Purpose

Protection of medicinal product developers' investments in generating the necessary preclinical and clinical data to obtain marketing authorisation against unfair commercial use. This creates incentives to make substantial investments in research and development.

Details

- 8+2 (+1) years
- 8 years of data exclusivity: generics 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 of one or more new indications are discovered within the first 8 years

Type of IP: Incentives for 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 enterprises (SMEs)
- New, additional indication or extension of existing RD indication, requires separate assessment by the EMA and authorisation decision by the European Commission

Type of IP: Incentives for Paediatric Medicinal Products

Historical purpose

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

Details

- 6-month extension of the Supplementary Protection Certificate (SPC) after submission of a Paediatric 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

Specific Aspect: The Roche-Bolar exemption in the EU

The so-called 'Roche-Bolar exemption' 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 authorisation documents (65).

2.6 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 anonymised data remotely. Further information is publicly available on the AMDC website such as the microdata catalogue, which contains the available register data, authorised research institutions, technical research institutions, technical and legal requirements for the application, ongoing projects, etc. (66). Unfortunately, there are only a few health data datasets currently available in the AMDC.

In order to further advance the digitalisation of the healthcare system in Austria in a structured manner, the focal points and priorities of implementation for the coming years are defined in the Austrian eHealth Strategy (67). The strategy was also designed with a view to the practical implementation of the **European Health Data Space (EHDS).**

The EU regulation on the European Health Data Space (EHDS) (68) was adopted at the beginning of 2025 after several years of negotiations. The regulation came into force on 1 March 2025 and applies with immediate effect in all EU member states. Details on the use of data within the framework of the EHDS will be regulated in further legal acts and guidelines in the coming years. Most of the regulations relevant to the practical use of the EHDS will not apply until 26 March 2029.

The central element of the EHDS is its focus on the common good: Structured collection, networking and careful use of electronic health data enable evidence-based decisions for optimised planning, high-quality care and future-oriented research. In addition to citizens of the European Union, regulatory authorities, political decision-makers and research institutions should benefit from the secure and transparently accessible data sets. As the first electronic health data space, the EHDS can also increase the EU's attractiveness as a future-orientated research location.

The EHDS distinguishes between primary and secondary use of the data. **Primary use** is intended to offer citizens and, where necessary, healthcare professionals, e.g. doctors, better digital access to electronic health data and thus improve healthcare provision at home and abroad. Citizens' control over their own health data and access to it from other EU member states should be made easier. This plays a decisive role not only for short-term stays abroad, but also for commuters and patients who deliberately want to use healthcare services in other EU member states.

To implement this in practice, each EU member state is to set up national access portals based on the **MyHealth@EU** platform (69). This will ensure access to patients' personal health data, such as patient summaries, electronic prescriptions (e-medication, e-prescription), medical images and image reports as well as laboratory results. Citizens should also be able to upload electronic health data themselves, for example via certain apps, with this being labelled accordingly in the electronic patient record.

The **secondary use** of data is intended to promote trustworthy scientific research, innovation and patient safety as well as the improvement of public healthcare systems, among other things. Data silos are to be broken down and the potential of the huge EU-wide treasure trove of data is to be utilised in the public interest subject to strict data protection requirements. Data protection is the top priority.

Personal data will not be shared for secondary use. Instead, the exchange of anonymised and often aggregated health data is envisaged, with the interoperability of data sets playing a decisive role in the successful reuse of existing information.

One aim of secondary data utilisation within the framework of the EHDS is to facilitate the further development of treatment options and medicinal products, from which patients benefit. The disclosure of data for advertising purposes or, for example, for the assessment of insurance applications is not permitted.

Nevertheless, citizens have the right to object to the use of secondary data in whole or in part (opt-out). EU member states can only provide exceptions to the right to opt out in certain situations. In the event of an opt-out, these data sets are also not available for future-oriented research from which both healthy and sick people would benefit.

Further information and updates on the announced supplementary legal acts and guidelines: European Health Data Space (EHDS) (70).

9,357

authorised human medicinal specialities
in Austria

100

authorisations for medicinal products in the EU
in 2025

215

new medicinal products in the last five years
in Austria, of which 46 in 2025

3. Medicinal Products: Manufacturing, Authorisation and Evaluation

3.1 Definition Medicinal Product

Medicinal Product

According to the Federal Act of 2 March 1983 on the Manufacture and Placing on the Market of medicinal products (Arzneimittelgesetz – AMG (71)), medicinal products are substances or preparations of substances which

1. Are intended for use in or on the human body and as agents with properties for curing or alleviating or preventing human diseases or pathological conditions, or
2. Can be used in or on the human body or administered to a human being in order to
   a) Restore, correct or influence physiological functions through a pharmacological, immunological or metabolic action, or
   b) Serve as the basis for a medical diagnosis.

Objects containing a medicinal product or to which a medicinal product is applied and which are intended to be administered to or in the human body are also considered to be medicinal products.

Active Substances

Active substances are substances or mixtures of substances that, when used in the manufacturing of medicinal products, become the pharmacologically active components of the medicinal product.

Excipients

Excipients are all components of a medicinal product with the exception of the active substance and the packaging material.

For medical applications, active substances are processed with excipients to form a medicinal product.

Speciality Medicinal Products

Speciality medicinal products are medicinal products which are always manufactured in advance in the same composition and placed on the market under the same name in a form intended for supply to the consumer or user, as well as medicinal products for supply to the consumer or user which are otherwise manufactured using an industrial process or which are manufactured commercially.

3.2 Types of Medicinal Products

A basic distinction is made between the following types of medicinal products in accordance with the Medicinal Products Act (71):

Chemically synthesised medicinal products are medicinal products that are produced by chemical synthesis.

Herbal medicinal products are all medicinal products which contain as active substances exclusively one or more herbal substances or one or more herbal preparations or one or more herbal substances in combination with one or more such herbal preparations.

Traditional herbal medicinal specialities must meet the following requirements for registration with the Federal Office for Safety in Health Care (BASG):

- The indications for use correspond exclusively to those of traditional herbal medicinal products which, according to their composition and intended use, are intended to be used without a prescription.
- They are to be administered exclusively in a specific strength and dosage and are intended exclusively for oral or external use or for inhalation.
- Proof of traditional use, including safety and plausibility of efficacy, is available.
- Use over a period of at least 30 years, including at least 15 years in the European Economic Area (EEA)

Homeopathic medicinal products are medicinal products which have been manufactured from homeopathic stocks in accordance with a homeopathic preparation described in the European Pharmacopoeia or, in the absence thereof, in accordance with a homeopathic preparation described in the pharmacopoeias in official use in the member states of the EEA.

A **generic medicinal product** is a medicinal product which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Biological medicinal products are medicinal products whose active substances are of biological origin or are produced from material of biological origin. These include immunological speciality medicinal products, speciality medicinal products manufactured using human blood or blood plasma as a starting material, biotechnologically manufactured medicinal products and advanced therapy medicinal products (71,72).

Biosimilars are the successor products of complex biological medicinal products and are equivalent to their reference products in terms of efficacy, safety and quality (73).

3.3 Medicinal Product Innovations

Medicinal products make a significant contribution to society by curing, alleviating or preventing diseases. Based on new scientific findings about biological processes or specific diseases, new medicines are developed that can be used to treat patients better or for the first time.

Medicinal products and medical progress also contribute significantly to a longer life. An analysis of data from the USA and 26 other high-income countries shows the connection 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 (74).

A 2021 study by the Institute for Advanced Studies (IHS) shows where and how innovative drug therapies work (75). In addition to medicinal products, innovations in healthcare also include diagnostic or therapeutic procedures whose effects go beyond the direct benefits for patients (longer 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. Preventive measures contribute to a benefit for society as a whole, as they help to avoid cases of illness. It leads to a reduction in the burden of disease both for those affected and for society as a whole if illnesses can be completely prevented.

The following examples show how innovative therapies can change the entire healthcare system and what opportunities they offer – above all to save lives and give sick people a better quality of life.

In the years 2023 to 2025, the European Medicines Agency (EMA) recommended 295 medicinal products for authorisation, 123 of which contained a new active substance. Most innovations in 2025 were in the fields of oncology (76–78).

	EMA recommendations for authorisation	Of which with new active substance
2023	77	39
2024	114	46
2025	104	38
Total	**295**	**123**

Source: EMA. Human medicines highlights of 2023, 2024, 2025 (76–78)

Innovations 2025 (78)

- 104 new medicinal products for human use were recommended for authorisation by the EMA.
- 38 of these contain new active substances.
- 16 medicinal products received confirmation of their status as orphan medicinal products.
- 41 biosimilars were approved by the Committee for Medicinal Products for Human Use (CHMP), the highest number ever approved.

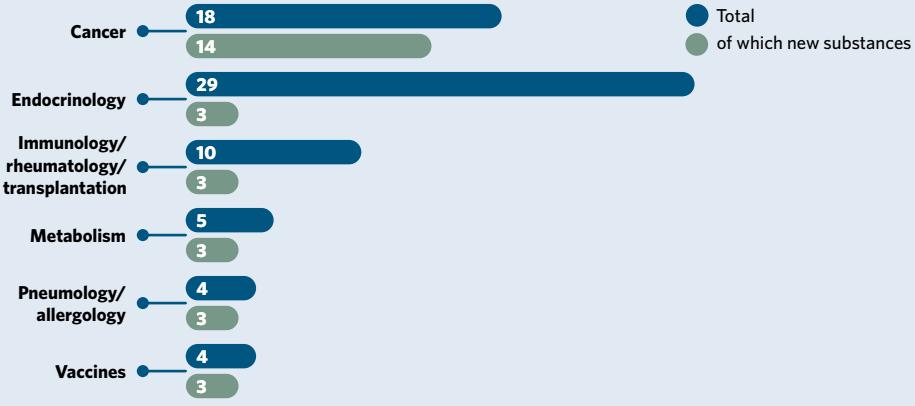
- 30 veterinary medicinal products were recommended for authorisation by the EMA.
- 13 of these contain new active substances (79).

The new authorisations are intended for the treatment of cancer, haematological diseases, immunological diseases of the central nervous system, the cardiovascular system and metabolism, among others.

Further recommendations by the EMA for authorisation (78)

- The first medicinal product for the treatment of Wiskott-Aldrich syndrome
- The first medicinal product for the treatment of non-cystic fibrosis bronchiectasis

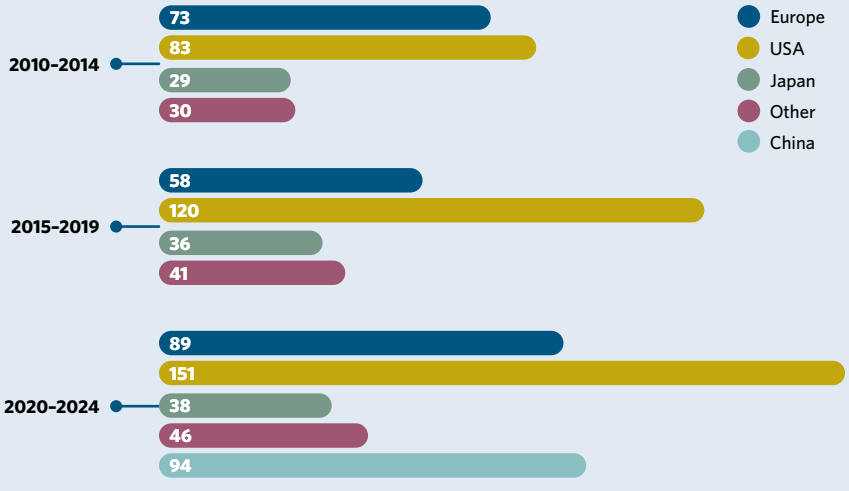
Selected* innovations per area



*Other: Cardiovascular system, Dermatology, Diagnostic agents, Endocrinology, Gastroenterology/hepatology, Haematology/haemostaseology, Immunology/rheumatology/transplantation, Infections, Metabolism, Neurology, Ophthalmology, Pneumology/allergology, Urology/nephrology
Absolute figures

Source: EMA - Human medicines in 2025 (78)

New substances by region



Absolute figures

Source: EFPIA – The Pharmaceutical Industry in Figures 2025 (80)

In the last five years, a total of **215 medicinal products** with a new active substance have been authorised in Austria. On average, 43 new treatment options are available each year.

Number of Innovations in Austria

2025	2024	2023	2022	2021
46	38	36	54	41

Absolute figures

Source: BASG 2026

3.3.1 Areas With a High Level of Innovation

Advanced Therapy Medicinal Products (ATMPs)

Advanced Therapy Medicinal Products (ATMPs) are medicinal products for human use that are based on genes, tissues or cells. They offer significant new possibilities for the treatment of diseases and injuries.

Types of ATMPs

ATMPs can be categorised into three main groups (81):

- **Gene therapy medicinal products:** They contain genes that lead to a therapeutic, prophylactic or diagnostic effect. They work by introducing 'recombinant' genes into the body, usually to treat a range of diseases, including genetic disorders, cancer or long-term illnesses. A recombinant gene is a section of DNA that is produced in the laboratory by combining DNA from different sources.
- **Somatic cell therapeutics:** They contain cells or tissues that have been manipulated to alter their biological properties, or cells or tissues that are not intended for the same essential functions in the body. They can be used to cure, diagnose or prevent diseases.
- **Bioengineered tissue products:** These contain cells or tissue that have been modified in such a way that they can be used to repair, regenerate or replace human tissue.

Regulatory Requirements

ATMPs are subject to strict regulatory requirements to ensure their safety, efficacy and quality. In the EU, ATMPs are regulated by Directive 2001/83/EC (82) and Regulation (EC) No. 1394/2007 (83) and are subject to Europe-wide authorisation in accordance with Regulation (EC) No. 726/2004 (72).

As of March 2026, 22 ATMPs are authorised in the EU, 19 of which are medicinal products for rare diseases (84):

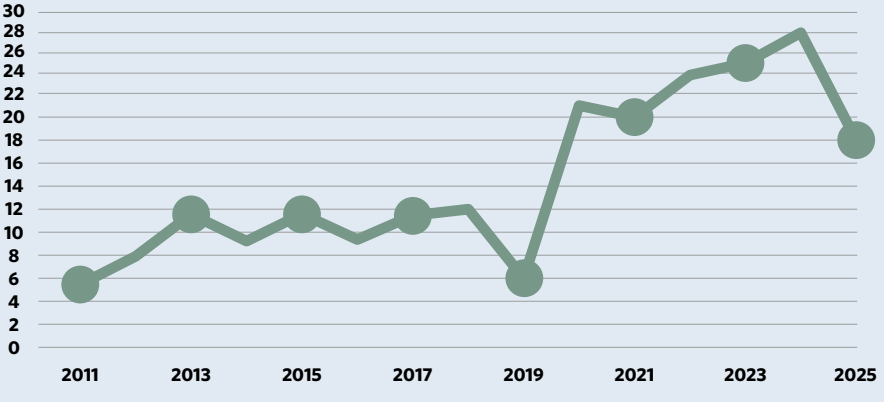
- 18 gene therapy medicinal products
- 2 (somatic) cell therapy products
- 2 biotechnologically processed tissue products

Medicinal Products for the Treatment of Cancer

In Austria, over 46,000 people are diagnosed with cancer every year. Currently, around 440,000 people live with a cancer diagnosis. The number of new oncological cases will continue to rise in the coming years due to the increasing share of older people. Although cancer is still the second most common cause of death in Austria, the chances of survival are increasing. This is primarily due to evidence-based and timely early detection, diagnosis and treatment (85,86).

- In 2025, the EMA recommended 18 medicinal products for authorisation, 14 of them with a new active substance (78).

Number of medicinal products for curing cancer recommended for authorisation



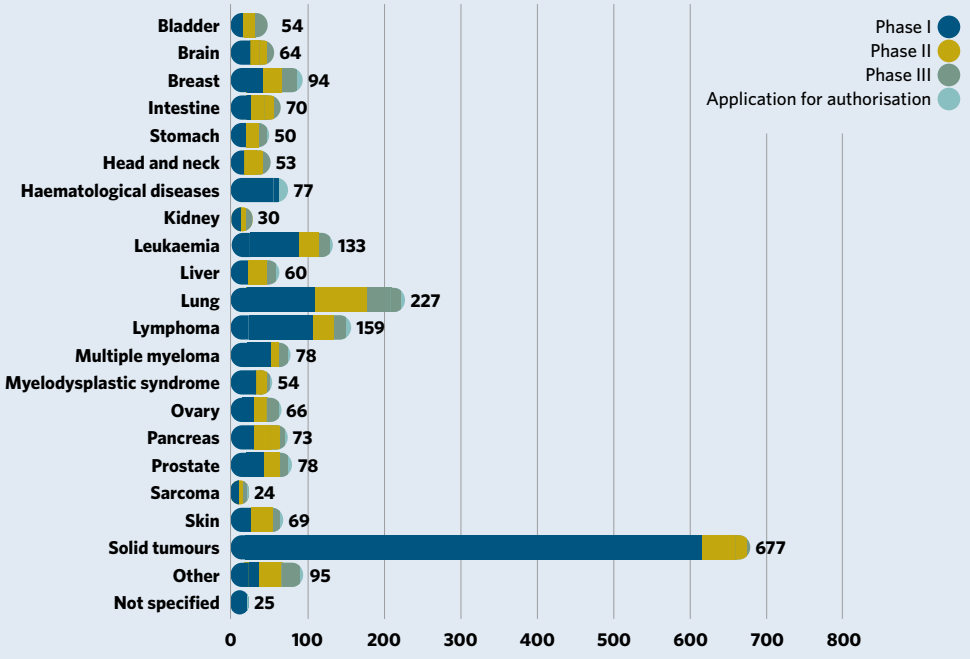
Source: EMA - Human medicines in 2025 (78)

Outlook

According to a survey by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), 5,250 medicinal products for the treatment of cancer were in development worldwide in October 2024 (62).

The IQVIA report Global Oncology Trends 2025 notes that the number of oncology trial starts rose slightly to 2,162 in 2024 (following declines since the 2021 peak). This represents an increase of 12 % compared to 2019. The majority of oncology trials focus on rare cancers: 74 % of trial starts in 2024 investigated medicines for rare cancers, an increase of 3 % compared to 2023. Innovative oncological treatment approaches such as cell and gene therapies, antibody-drug conjugates (ADCs) and multispecific antibodies show considerable potential in cancer treatment and accounted for 35 % of all oncology trials in 2024 (87).

Medicinal products and vaccines in development against cancer



Source: PhRMA. MEDICINES IN DEVELOPMENT FOR CANCER – 2023 Report (88)

Oncology is also the most researched therapeutic area in Austria (approx. 43% of industry-sponsored clinical trials) (see Section 2.2 Clinical Research) (89).

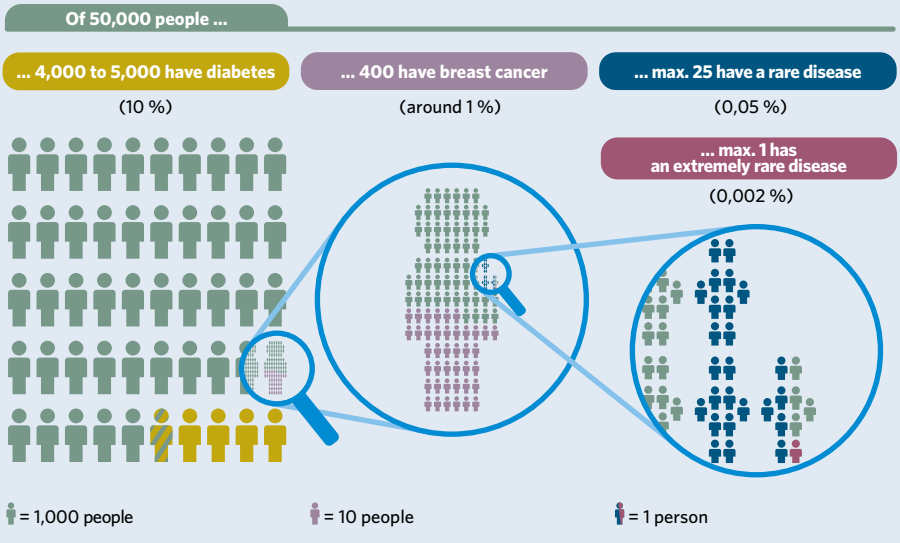
Medicinal Products for the Treatment of Rare Diseases

Rare diseases are life-threatening or chronically debilitating diseases that occur more frequently in the population than is generally assumed. An estimated 36 million people in the EU are currently affected. In the European Union, a disease is considered rare if it affects fewer than five people in 10,000 (90). Of the approximately 30,000 known diseases, more than 6,000 are rare diseases; around 70 % of rare diseases already manifest in childhood. 72 % of rare diseases are genetically determined. Other causes include infections (both bacterial and viral), allergies or environmental factors. In Austria, around 450,000–500,000 people (corresponding to 5 % of the population) suffer from rare diseases (91).

Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products (92) was adopted in 2000 specifically to promote the research and development of medicinal products for rare diseases, so-called orphan drugs, by pharmaceutical companies. It offers companies reduced authorisation fees and marketing rights for ten years.

The prerequisite for this is an application for orphan drug status (= designation) to the EMA, which can be submitted at any time during the development of such a medicinal product before the authorisation application is submitted. As with other medicinal products, the subsequent review of the authorisation application is carried out by the Committee for Medicinal Products for Human Use (CHMP) in a centralised procedure (90).

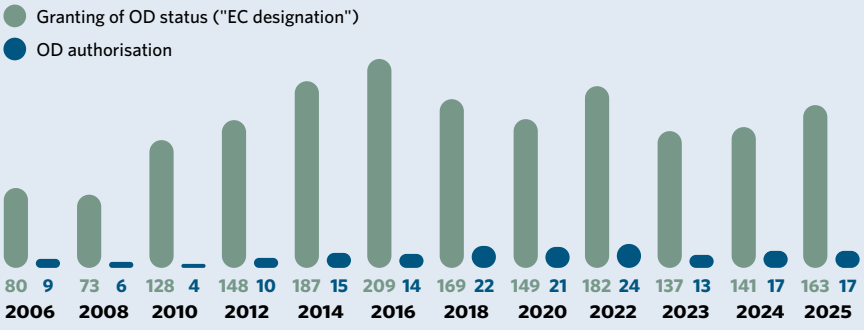
What is rare? A comparison



Source: PHARMIG

Between 2000 and 2025, 4,797 applications for orphan drug designation were submitted. Of these, 3,175 received the designation, and of those only 278 have so far obtained marketing authorisation as an orphan drug. The high number of applications reflects the encouragingly high level of research activity in this area and shows that the incentives offered by the regulation are being taken up. However, the low success rate also illustrates the high entrepreneurial risk. In 2025, 17 orphan drugs were authorised (93).

Orphan drugs 2006 to 2025
Granting of status vs. authorisation



Figures in absolute terms

Source: EMA – EU report orphan contribution 2025 (93)

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

The NAP.se was published at the end of February 2015 – with the aim of improving the lives of all affected patients and their relatives. It was drawn up on behalf of the Federal Ministry of Health by the National Coordination Centre for Rare Diseases (NKSE) in collaboration with the Expert Group for Rare Diseases and the Strategic Platform for Rare Diseases (94).

European requirements (e.g. recommendations, guidelines), the national needs assessment 'Rare Diseases in Austria' (95), the structured exchange with national experts and current national points of reference such as the framework health goals, the health reform or the child and youth health strategy formed the starting point for the development.

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

The NAP.se (94) as well as the evaluation of the report (2020) (96) and information on the centres of expertise (97) can be found on the website of the Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection (94).

Vaccines

Vaccinations are considered one of the most effective measures to prevent diseases. According to the WHO, the widespread use of vaccines (excluding COVID-19) prevents four to five million deaths a year from diphtheria, tetanus, whooping cough, influenza and measles. An increase in global immunisation coverage rates could prevent a further 1.5 million deaths (98). Today, more than 20 infectious diseases and infection-associated cancers can be prevented by immunisation (99).

Types of Vaccines

The different types of vaccines include (100,101):

Live Vaccines

Live vaccines use a weakened (or attenuated) form of the pathogen that causes a disease. As these vaccines are very similar to the natural infection they are intended to prevent, they cause a strong and long-lasting immune response. Live vaccines include those against measles-mumps-rubella (MMR), varicella (chickenpox) and rotavirus.

Inactivated Vaccines

Inactivated vaccines contain dead pathogens or parts of them that can no longer multiply. Inactivated vaccines generally do not produce as strong an immune response as live vaccines. Therefore, several booster immunisations may be required to achieve long-term immunity against diseases. Inactivated vaccines are used to protect against the following diseases: Hepatitis A, influenza, TBE and tetanus.

mRNA Vaccines

mRNA vaccines contain 'building instructions' in the form of mRNA for a specific component of a virus. These instructions enable the body to produce this component itself. As a result, the immune system produces antibodies against this part of the virus. mRNA vaccines are used, for example, to protect against Covid-19.

Vector Vaccines

Vector vaccines are genetically modified vaccines that contain the genetic code of a pathogen. This code is introduced into the body using a vector. A vector is a harmless virus that functions as a means of transport. As soon as the vector virus has introduced the genetic information into the body, it simulates an infection. This leads to the production of antibodies against the pathogen. Vector vaccines include the Ebola vaccine and certain COVID-19 vaccines.

Subunit, Recombinant, Polysaccharide and Conjugate Vaccines

These vaccines only use certain parts of the pathogen, such as a protein, the sugar or the capsid (envelope around the germ). They are used to protect against the following infections: Haemophilus influenzae type B, hepatitis B, HPV (human papillomavirus), whooping cough, pneumococcus, meningococcus and shingles.

Vaccines – like all medicinal products on the market – are strictly monitored for safety during the development and manufacturing process (see chapter 4 Monitoring Medicinal Products) (100).

Vaccine Research

Europe is working intensively on the development of new vaccines. An evaluation by Vaccines Europe shows that the vaccine manufacturers' pipelines are well filled. At the end of August 2025, there were 91 vaccine candidates in the pipeline, 86 of which were prophylactic vaccines and five therapeutic vaccines (against infectious agents) (102).

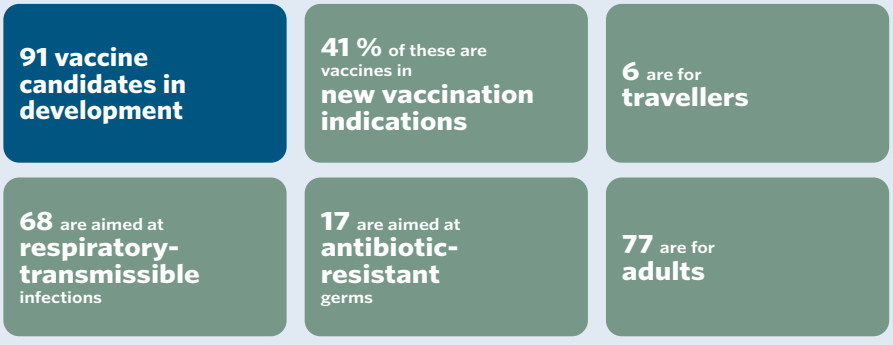
The most common vaccine candidates:

- Seasonal influenza: 13
- Pandemic influenza: 8
- Pneumococcal diseases: 8
- COVID-19/SARS-CoV-2: 7
- Respiratory syncytial virus (RSV): 6

In addition, several vaccine candidates are in development that target a combination of these viruses (COVID-19, influenza, RSV).

41% of the vaccines under development are intended to combat diseases for which no vaccines are currently available, such as acne, borrelia, Epstein-Barr virus or HIV. In addition, 17 vaccine candidates are directed against antibiotic-resistant bacteria, 7 of which are on the WHO's list of priority bacterial pathogens.

Overview of the Vaccine Pipeline in Europe



Source: Vaccines Europe pipeline review 2025 (102)

Authorised Vaccines in Austria

The Federal Office for Safety in Health Care (BASG) publishes a list of all vaccines currently authorised in Austria on its website (103).

3.4 Requirements for Medicinal Products

The EU regulatory framework for medicinal products for human use sets standards that ensure a high level of protection of public health and the quality, safety and efficacy of medicinal products (104).

The authorisation of medicinal products is based on three key criteria, namely safety, efficacy and quality, to ensure that the products administered to patients are of appropriate quality and have a positive risk-benefit balance.

Safety and Efficacy of Medicinal Products

The safety and efficacy of medicinal products are of crucial importance. When authorising medicinal products, companies must demonstrate safety and efficacy based on the results of clinical trials.

The data on the efficacy, safety and quality of the medicinal product are reviewed by the competent authorities before a product is authorised. A medicinal product is only authorised if the risk-benefit profile is appropriate and the benefits outweigh the risks.

Safety and efficacy are also monitored after authorisation through pharmacovigilance activities and review of the risk-benefit ratio.

Quality of Medicinal Products

When applying for a marketing authorisation, companies must submit documentation demonstrating that the medicinal product has been manufactured in compliance with the required quality standards. These are assessed on the basis of criteria laid down in EU legislation.

3.5 Manufacturing and Quality Assurance

Area of Pharmaceutical Manufacturing

Under the Austrian Medicinal Products Act (AMG, § 2) (71), the general term "manufacturing" covers the extraction, production, preparation, treatment or processing, transfer (including filling) and packaging of medicinal products or active substances, as well as the labelling of speciality medicinal products. Medicinal product manufacturing encompasses the targeted pharmaceutical production, testing and provision of medicinal products of consistent quality.

Under controlled conditions, tested, ready-to-use medicinal products are manufactured in the desired dosage form. These may be solid, such as tablets and capsules; liquid, such as drops and syrups; semi-solid, such as ointments; gaseous, such as inhalation sprays; or they may be special dosage forms, such as suppositories, patches and solutions for injection.

The manufacturing of medicinal products is regulated by national, European and international regulations. Pharmaceutical manufacturers require an official manufacturing authorisation, for the granting of which suitable and sufficient premises, technical facilities and control options must be available. In addition, in order to obtain a manufacturing authorisation, every manufacturer must have a Qualified Person (QP). The Qualified Person is responsible for ensuring that each batch of a medicinal product has been manufactured and tested in accordance with Good Manufacturing Practice (GMP) and other regulations, in particular the documents on which the marketing authorisation is based (71,105).

Quality Assurance Guidelines

Quality assurance plays a central role in pharmaceutical manufacturing, as quality deviations can have a direct impact on patient health. GMP ensures that medicinal products are manufactured to a consistently high quality, are fit for their intended use and meet the requirements of the respective marketing authorisation. GMP refers to the guidelines for the quality assurance of production processes and the production environment in the manufacture of medicinal products and active substances (106).

Part I of the EU GMP Guide contains nine chapters that define the rules for the GMP-compliant manufacture of medicinal products (107). Part II covers the basic requirements for active substances used as starting materials, while Part III lists GMP-related documents. Part IV addresses the GMP requirements for advanced therapy medicinal products (ATMPs) (107). Supplementary annexes expand the guide and specify particular GMP requirements. They define binding standards for numerous areas relating to the manufacture of medicinal products. There are currently 21 of these annexes.

National and International Organisations and Regulations in the Field of GMP

At EU level, the GMP guidelines are drawn up by the European Commission with the involvement of the European Medicines Agency (EMA); in the USA, the Food and Drug Administration (FDA) issues current good manufacturing practice (cGMP) regulations.

The ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) is responsible for the global harmonisation of quality standards, which is implemented through the development of ICH guidelines (108).

The Pharmaceutical Inspection Co-operation Scheme (PIC/S (109)) also operates at international level and is responsible for cooperation between the GMP inspection authorities. Its aim is the global harmonisation of inspection procedures through the development of common GMP standards. In Austria, the implementation into national law is carried out through statutory provisions, in particular the Medicinal Products Act (AMG), the Ordinance on Pharmaceutical Establishments (AMBO) and other relevant legislation. Responsibility for monitoring compliance with the statutory provisions lies with the Federal Office for Safety in Health Care (BASG), supported by the Austrian Agency for Health and Food Safety – Medicines Market Surveillance (AGES MEA) as its operational partner.

3.6 Authorisation Procedures

Medicinal products may only be placed on the market by the marketing authorisation holder if they have been officially authorised or registered.For an authorisation, 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. A marketing authorisation for a speciality medicinal product and a registration of a traditional herbal, homeopathic or speciality pharmacy medicinal product are generally valid for five years.The marketing authorisation holder can submit an application for the extension of the marketing authorisation or registration at the earliest four years after the authorisation or registration decision has become legally valid and at the latest nine months before the expiry of five years after the authorisation or registration decision has become legally valid (71).

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

- **National Procedure**
  The (purely) national authorisation procedure can only be used for a medicinal product that is to be authorised exclusively in one European country.
- In Austria, the assessment and granting of authorisation is carried out by the BASG (Federal Office for Safety in Health Care). Legal basis: National Medicines Act of the EU member state. In Austria, the Federal Act of 2 March 1983 on the Manufacture and Placing on the Market of Medicinal Products (Arzneimittelgesetz- AMG) (71).
- **Mutual Recognition Procedure (MRP) / Decentralised Procedure (DCP)**
  These authorisation procedures are used when a medicinal product is to be authorised in more than one EU member state. The principle of the procedures is the mutual recognition of an authorisation by the other member states. The MRP is to be applied if an authorisation already exists in a member state. The DCP is only possible if there is no corresponding authorisation in this country yet. The applicant is free to choose the member states in which the medicinal product is to be authorised. The basic prerequisite is the approval of all participating authorities of the EU member states for the application for authorisation. Each member state issues a national marketing authorisation at the end of the procedure. Legal basis: Directive: 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (82).

Central Procedure (EU)

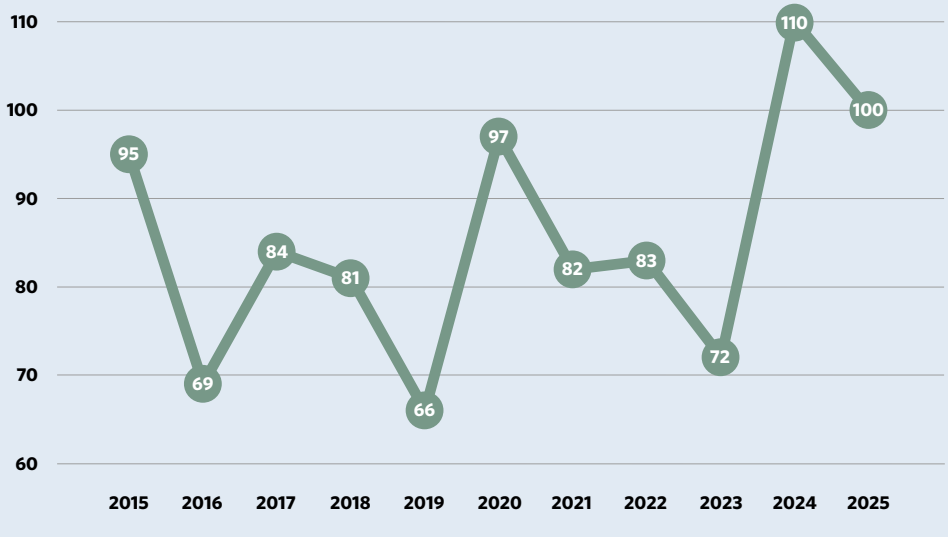
Since 1995, there has been a central authorisation procedure in which a European authorisation is issued at the end. The central authorisation is issued by the EU Commission and is valid in all EU member states. Legal basis: Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (72).

The central authorisation procedure is mandatory for biotechnological medicinal products, medicinal products for rare diseases and medicinal products for human use with **new active substances** for the following therapeutic indications:

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

This procedure is coordinated by the European Medicines Agency (EMA) based in Amsterdam. Two national authorities (Rapporteur and Co-Rapporteur) carry out the assessment 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 issues an EU marketing authorisation that is valid for all member states.

Number of new EU authorisations for medicinal products

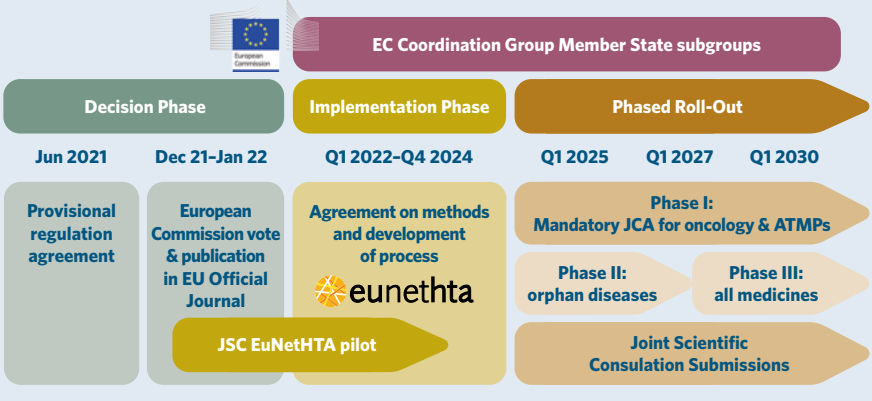


Source: Europäische Kommission – Union Register of medicinal products (110)

3.7 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 cost bearers 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 has been applied since January 2025 (111). It regulates how health technology assessments are to be carried out at European level.

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 (112).



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 within 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 medicinal products, remains the responsibility of the member states.

3.8 Authorised and Registered Human Medicinal Specialities in Austria

If a medicinal product is authorised under the Medicinal Products Act, it is referred to as a 'medicinal speciality'. The responsible authority in Austria is the Federal Office for Safety in Health Care (BASG) (113).

The legal basis is the Health and Food Safety Act (GESG) (114).
(medicinal products for human use incl. homeopathic medicinal products)

Number of authorised human medicinal products 2025*	9,357
Chemical medicinal products	8,238
Homeopathic medicinal products	518
Biological medicinal products	355
Herbal medicinal products	41
Radiopharmaceuticals	159
Medical gases	46

*excl. EU authorisations

Source: BASG-Statistiken zu Arzneispezialitäten (115)

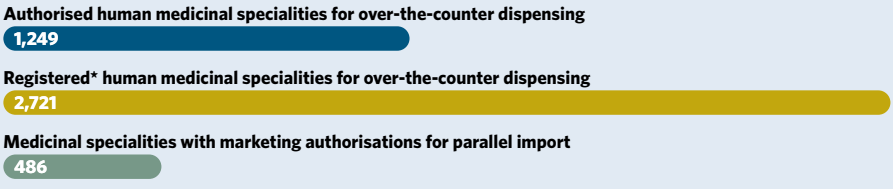
Number of registered human medicinal speciality products 2025	2,884
Homeopathic medicinal products	1,905
Pharmacy's own medicinal products	605
Traditional herbal registrations	211
Allergen manufacturing processes	163

Source: BASG-Statistiken zu Arzneispezialitäten (115)

3.9 Prescription Requirements of the Authorisations

The prescription-only status of a medicinal product is also determined as part of the authorisation procedure. The legal basis for this is the Prescription Obligations Act (Rezeptpflichtgesetz) and the Prescription Obligations Ordinance (Rezeptpflichtverordnung) (116,117).

Prescription-only Status 2025



Figures in total | As at 21 January 2026 | *Homeopathic and Traditional Herbal Medicinal Products

Source: BASG-Statistiken zu Arzneispezialitäten (115)

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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.

4. Pharmacovigilance

4.1 Pharmaceutical monitoring by regulatory authorities

Pharmacovigilance includes the science 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 adverse reactions 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, in particular by providing timely information to patients, users and the public on the safety of medicinal products.

Pharmacovigilance contributes to the protection of patients and public health.

In Austria, the BASG (Federal Office for Safety in Health Care) is a subordinate authority reporting to the BMASGPK (Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection). The BASG is responsible for the monitoring of medicinal products after authorisation, including combating illegal activities on the medicines market (113).

Pharmacovigilance System

The pharmacovigilance system serves the marketing authorisation holders and the competent authorities of the EU member states to fulfil their tasks and responsibilities under Title IX of Directive 2001/83/EC (82). It monitors the safety of medicinal products and detects any changes in their benefit-risk ratio (assessment of the positive therapeutic effect of the medicinal product in relation to the risks in terms of quality, safety, and efficacy).

The **Good Pharmacovigilance Practices (GVP) modules** of the **European Medicines Agency (EMA)** are a set of guidelines and measures intended to standardise and facilitate the conduct of pharmacovigilance activities in the European Union (118).

4.2 Post-authorisation Pharmacovigilance

The European Commission or the national authorities decide on the authorisation of medicinal products after assessing the results of preclinical and clinical trials. Only medicinal products whose benefits demonstrably outweigh the risks are authorised. This ensures that patients have access to the treatments they need without being exposed to unacceptable adverse reactions.

Since clinical trials are conducted under controlled conditions with limited numbers of participants, rare or unexpected adverse reactions may only emerge after market launch. In widespread use, medicinal products are administered to a heterogeneous group of patients – often with pre-existing conditions or concomitant medication. Continuous monitoring of medicinal product safety is therefore necessary in order to detect new risks such as adverse reactions and interactions at an early stage and, where appropriate, to initiate risk-minimisation measures.

The Black Triangle

The European Union has introduced labelling 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 medicinal products 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 medicinal products:

- Medicinal products containing a new active substance that was authorised in the EU after 1 January 2011.
- Biological medicinal products (e.g. vaccines, plasma-derived medicinal products) authorised in the EU after 1 January 2011.
- Medicinal products with a conditional marketing authorisation or a marketing authorisation in exceptional circumstances.
- Medicinal products for which further studies need to be conducted (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 authorised if recommended by the Pharmacovigilance Risk Assessment Committee (PRAC) (119).

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

Adverse Reaction Reporting and Assessment

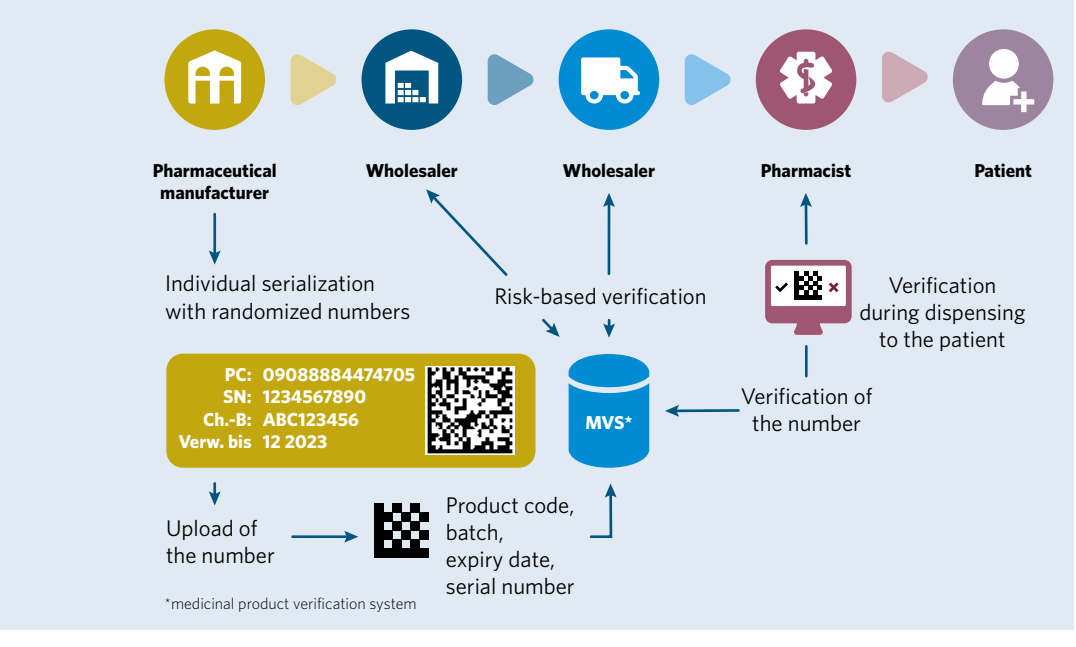
An adverse reaction is understood to be any unintended and harmful reaction to a medicinal product. Reactions that occur as a result of medication errors, "off-label use" and overdose are also considered adverse reactions. After authorisation, medicinal products are systematically monitored and evaluated by the marketing authorisation holders and the medicines authorities in order to identify previously unknown adverse reactions or changes in their frequency. The most important source of information for this is spontaneous reports: healthcare professionals such as doctors and pharmacists are legally obliged to report suspected adverse reactions occurring in Austria to the BASG. Patients and their relatives have the option of voluntarily reporting suspected adverse reactions to medicinal products to the BASG. An online reporting form is available for this on the BASG website at nebenwirkung.basg.gv.at.

The BASG records suspected adverse reactions received via the national reporting portal, assesses them and, in accordance with EU requirements, transmits them to the EMA's EudraVigilance database. There, the data are stored and analysed by the PRAC as part of signal assessment. New findings may lead to changes in the Summary of Product Characteristics (SmPC) and package leaflet or to further risk-minimisation measures in order to ensure safe and effective use.

4.3 Counterfeit Protection Measures

The detailed legal requirements for the traceability of medicinal product packages are laid down at the EU level by Delegated Regulation (EU) 2016/161 (120). These regulations have been applicable since 9 February 2019.

Coding and Serialisation of Medicinal Products



Source: EFPIA

Delegated Regulation (EU) 2016/161 requires two safety features on the packaging of prescription medicinal products 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.

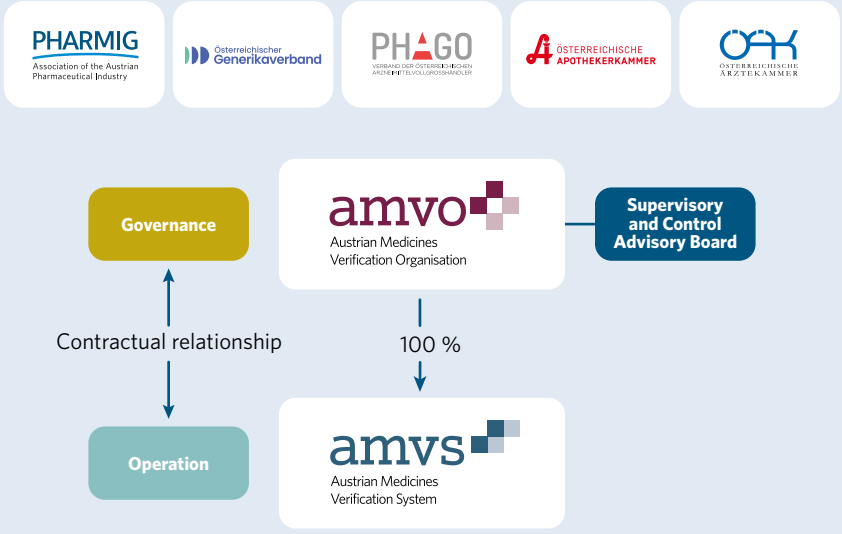
Implementation in Austria

In Austria, the AMVO (Austrian Medicines Verification Organisation) is responsible for the governance of the medicinal product verification system. The AMVO also publishes 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.

Since 9 February 2026, the digital safety system for medicinal products has been in live operation in Austria. Since then, all statutory requirements for the serialisation and verification of prescription-only medicinal products have applied without restriction. All verifying and dispensing parties must carry out the verification, deactivation and reactivation steps in accordance with the applicable legal and contractual requirements. The aim is a secure, stable and legally compliant operation of the system. A pack may only be dispensed once any alert that occurs has been resolved and a permissible corrective measure has been implemented (121).

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



Source: PHARMIG

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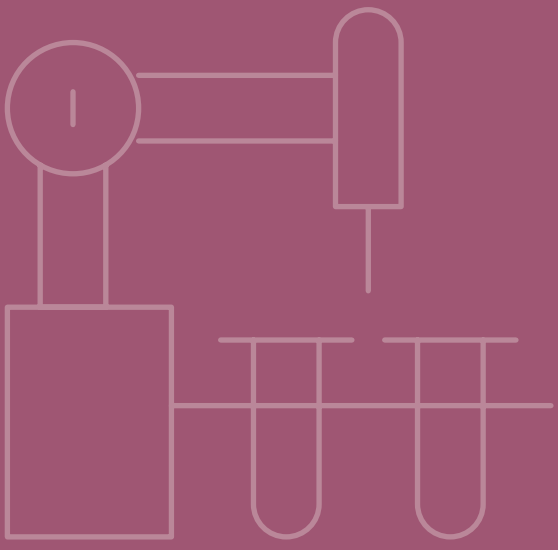
Total economic value added by the pharmaceutical industry in Austria approximately

12.9 billion euros

This corresponds to a contribution by the pharmaceutical industry of

2.9 %

to the Austrian gross domestic product.



5. Pharmaceutical Industry as an Economic Factor

5.1 Importance of the Pharmaceutical Industry Globally

According to a study by the independent WifOR Institute, the pharmaceutical industry makes a significant contribution to global gross domestic product (GDP). The economic impact of the global pharmaceutical industry is evident in two ways.Through the manufacture of pharmaceutical products, the industry contributes directly to global GDP and employs a large number of workers. In addition, the global pharmaceutical industry contributes to additional value creation and employment through its economic activity, as it is dependent on global supply chains. These indirect economic effects and the economic effects induced by private consumption are considered the economic spillover effects of the global pharmaceutical industry (122).

2,295 billion USD
Contribution of the pharmaceutical industry to global GDP 2022

755 billion USD
direct

*direct and spillover effects

Source: WifOR. The Economic Impact of the Global Pharmaceutical Industry (122)

74.9 million
Total number of jobs supported by the pharmaceutical industry 2022

7.8 million
direct

44.7 million
indirect

22.4 million
induced

Source: WifOR. The Economic Impact of the Global Pharmaceutical Industry (122)

5.2 Importance of the Pharmaceutical Industry in Europe

According to a survey by the auditing and consulting firm PwC, the pharmaceutical sector contributed a gross value added of 311 billion euros and 2.3 million jobs to the economy of the 27 EU states in 2022 (123).

311 billion euros
Contribution of the pharmaceutical industry to gross value added in the EU in 2022

163 billion euros
direct

68 billion euros
indirect*

80 billion euros
induced**

*indirect: through the EU27 supply chain; **induced: through employee spending

Source: PwC. Economic Footprint of the Pharmaceutical industry in Europe (123)

The total gross value added by the pharmaceutical industry in the 27 EU member states increased by 7.6% per year in real terms between 2016 and 2022.

2.3 million
Total number of jobs supported by the pharmaceutical industry in 2022

633,200	737,500	924,200
direct	indirect	induced

Source: PwC. Economic Footprint of the Pharmaceutical industry in Europe (123)

The pharmaceutical industry's contribution to total employment in the 27 EU member states increased by 2.1% per year between 2016 and 2022 (80).

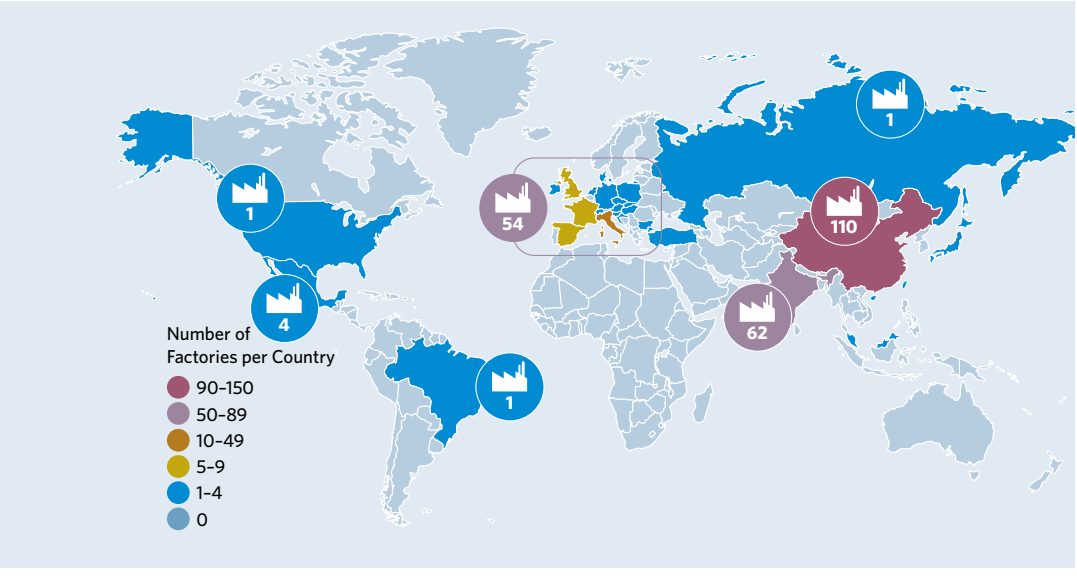
European comparison of pharmaceutical production in 2023

Country	Production in million euros
Ireland	67,682
Italy	52,000
Switzerland	48,864
Germany	37,597
United Kingdom	30,503
Denmark	29,701
Belgium	29,148
Spain	23,211
Sweden	12,228
Slovenia	11,589
Netherlands	7,328
Portugal	3,432
Hungary	3,410
Austria	**3,284**

Source: EFPIA - The Pharmaceutical Industry in Figures (80)

In 2023, Ireland, Italy, Switzerland and Germany were responsible for the majority of pharmaceutical production in Europe (80).

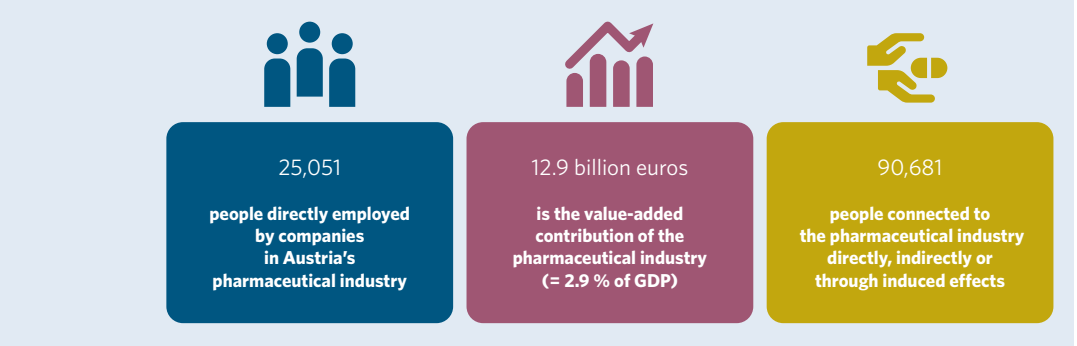
However, the example of antibiotic active substances shows how much Europe is dependent on Asia for the production of pharmaceuticals. For example, 60 % of active substance manufacturers are based in China or India (124).



Source: Pro Generika (124)

5.3 Importance of the Pharmaceutical Industry in Austria

The pharmaceutical industry makes a substantial contribution to the overall economic value added, to employment and to Austria's external economic position. Against the backdrop of increasing global competition between locations, geopolitical uncertainties and growing demands on security of supply, the role of the pharmaceutical industry and that of the life sciences industry is becoming ever more important.



Source: ECO AUSTRIA. Wertschöpfungswirkungen der pharmazeutischen Industrie in Österreich, März 2026 (41)

5.3.1 Manufacture of Pharmaceutical Products

A 2026 study by ECO Austria on the value-added effects of the pharmaceutical industry in Austria shows that the pharmaceutical industry is one of the strategically most important industrial and knowledge-based sectors in Austria (41).

According to the preliminary figures of Statistik Austria's Structural Business Statistics for 2024, a total of 128 companies were primarily engaged in the manufacture of pharmaceutical products. In Austria, around 91,000 employees, or 1.9 % of the working population, are connected to the pharmaceutical industry directly, indirectly or through induced effects. Of these, around 25,000 jobs are attributable to direct employment. The production of pharmaceutical products encompasses the manufacture of both patent-protected medicinal products and generics. At product-group level, the main products manufactured are antibiotics, biological medicinal products (including biosimilars), generics, vaccines, plasma derivatives and cytostatics (oncology medicines).

According to the Generics Association, four generics companies in Austria have their own production sites. They contribute around 2.5 billion euros to the overall economic value added of the pharmaceutical industry, thereby accounting for around 20 % of the total impact.

Increase in the Production of Pharmaceutical Products

Pharmaceutical production has expanded considerably over the past five years. Until 2019, the volume of pharmaceutical production developed in line with that of industrial production. Since 2022, a sharp increase has been observed in the pharmaceutical industry (41).

Compared to 2023, when pharmaceuticals worth 3.284 billion euros were produced in Austria, production rose very markedly in 2024, to 4.782 billion euros (125). This increase can be attributed to the expansion of existing production capacities and the establishment of new ones in Austria (41).

5.3.2 Marketing and Distribution of Pharmaceutical Products

Trade balance at the level of pharmaceutical products 2024

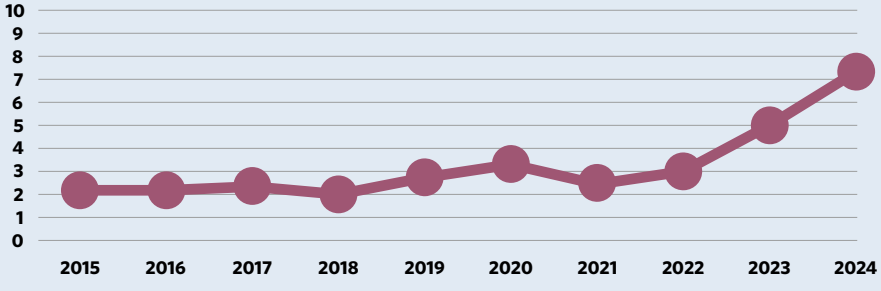
in million euros | as at: March 2026

Source: Institut für Pharmaökonomische Forschung; STATISTIK AUSTRIA, Güterproduktion nach ÖCPA und ÖPRODCOM

Austria is one of the exporting countries in the pharmaceutical industry: in 2024, Austria had a positive trade balance (8,214 million euros), meaning that more goods were exported than imported (126).

The trade balance rose significantly from around 2.5 billion euros in 2015 to approximately eight billion euros in 2024. This shows that pharmaceutical production makes an important contribution to exports and thus to Austria's economic development (41).

Development of the trade balance



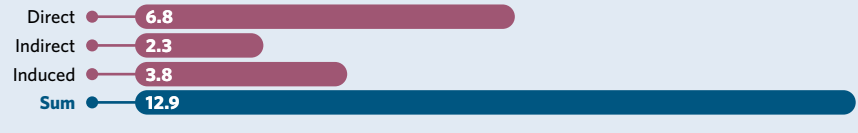
Net balance in billion euros

Source: ECO AUSTRIA, Wertschöpfungswirkungen der pharmazeutischen Industrie in Österreich, März 2026 (41)

5.3.3 Overall Economic Impact of the Pharmaceutical Industry

The pharmaceutical industry is associated with value-added effects of approximately 12.9 billion euros, with the majority of the effects – around 6.8 billion euros – attributable to direct effects. In 2024, the overall economic impact of the pharmaceutical industry thus amounted to around 2.9 % of Austria's gross domestic product (41).

Direct, indirect and induced economic effects of the pharmaceutical industry in Austria



Figures in billion euros

Source: ECO AUSTRIA, Wertschöpfungswirkungen der pharmazeutischen Industrie in Österreich, März 2026 (41)

5.4 Special Sub-sectors of Austria as a Pharmaceutical Location

5.4.1 Austria as a Plasma Location

Since the middle of the 20th century, a strong network of researchers, pharmaceutical companies and production facilities has developed in Austria, which has built up globally recognised expertise. Today, Vienna is one of the largest locations for processing human blood plasma into life-saving medicines. In the plasma fractionation process, therapeutically useful proteins such as immunoglobulins, albumin and coagulation factors are extracted from donated plasma. This highly complex process often takes several months and is subject to the strictest quality and safety standards.

There are numerous possible applications for medicinal products made from human blood plasma (currently more than 80 authorised medicinal products in Austria), such as

- the treatment of congenital and acquired immunodeficiencies,
- haematology including haemophilia (bleeding disorder),
- for serious injuries and burns (for haemostasis and wound closure),
- liver diseases,
- for severe infections (e.g. COVID-19),
- for neurological diseases,
- for oncological diseases,
- as blood coagulation products in operating theatres and intensive care units and
- for lung diseases (alpha 1-antitrypsin deficiency).

Cooperation between local research and development facilities, 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 over 60 years, making it the longest tradition in Europe.

Contribution of **plasma production** in Austria to local economic performance:

- 26 plasma centres with more than 600 employees
- Donation of 536,000 litres of plasma per year (2024)
- 58 litres plasma per 1,000 inhabitants (127)
- Contribution of 1.5 to 5 million euros per plasma centre each year

This makes Austria one of the world leaders in plasma production and a leader in Europe.

Contribution of **plasma processing** to local economic performance:

- Two plasma processing companies with a capacity of 7 to 8 million litres of plasma each year (7.7 to 8.8 % of global capacity) (128)
- Creation of around 10,000 jobs (full-time equivalents) by the plasma industry in Austria (127)
- Sustainable value creation also through job creation at supplier companies that supply the sites
- Export to over 100 countries

Austria guarantees a continuous chain of plasma production: from the extraction of plasma components to the formulation of medicinal products. The fully integrated production of high-quality medicinal products includes all steps from the raw material to the packaged end product.

5.4.2 Vaccine Production in Austria

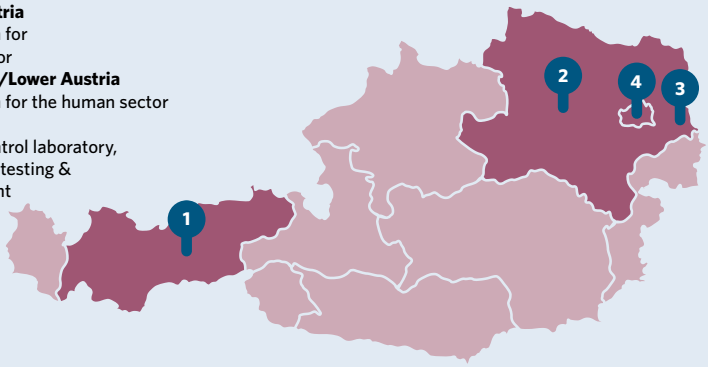
There are only a few pharmaceutical companies in the world that specialise in the complex production of vaccines. Vaccines are highly complex pharmaceutical products that require lengthy production processes (around 12 to 36 months) and a large number of control procedures. Austria plays an important role in vaccine research and production.

Five vaccine manufacturing companies have research and/or production sites in Austria. A further four operate purely as sales organisations in Austria.

In the human vaccine sector, for example, there is a large vaccine research centre in the Vienna Bio Center, a vaccine production facility in Orth a. d. Donau, a vaccine antigen production facility (= partial production of a vaccine) in Kundl in Tyrol and a veterinary vaccine production facility in Krems (129).

Sites with vaccine research and production in Austria

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



Source: Österreichischer Verband der Impfstoffhersteller (ÖVIH) (129)

Vaccine Production in Europe

Every year, 1.7 billion doses of vaccine are produced in Europe. This corresponds to 76% of global demand. Europe has 12 research centres and 27 production sites in 11 countries (130).

5.4.3 Antibiotics Production in Austria

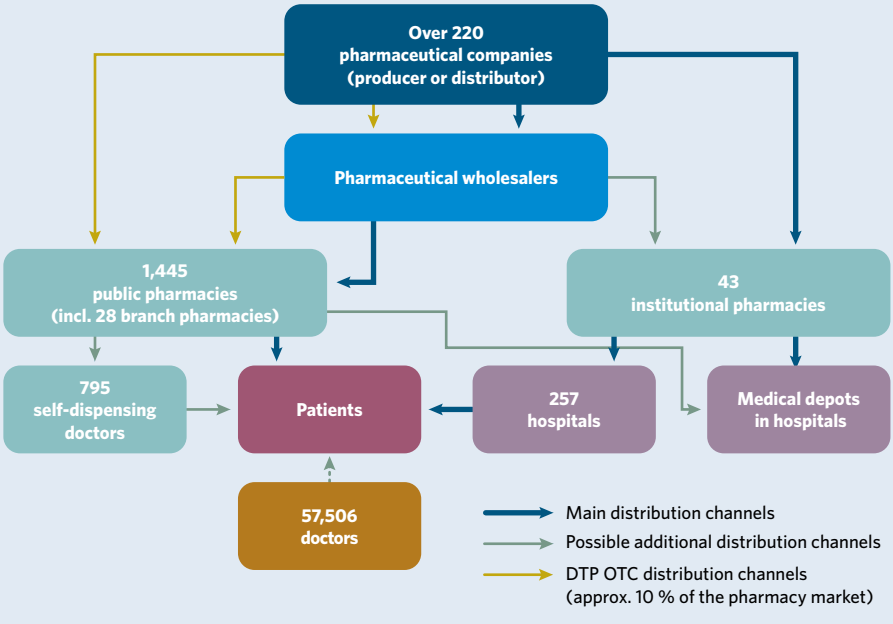
Austria is an important location for the production of antibiotics. Kundl, the last major centre of antibiotic production in Europe, has a production capacity of 4,400 tonnes of active substances and more than 240 million medicinal product packages per year – enough to cover the entire European demand for life-saving antibiotics. Today, over 100 countries are supplied with antibiotics 'Made in Austria'.

In addition to the significant quantity, Austria is also characterised by the way in which antibiotics are produced: From fermentation to the active substance to the finished form, the entire production process takes place at a single location, from the active substance to the finished packaged antibiotic tablet. This is unique in Europe (131).

5.5 Distribution of Medicinal Products

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

Pharmaceutical Supply Structure 2025



Source: PHARMIG, STATISTIK AUSTRIA, Österreichische Apothekerkammer, Österreichische Ärztekammer (19–21)

Around one third of the pharmaceuticals were sold to hospitals and two thirds to public pharmacies and the extramural sector (by value) in 2024.

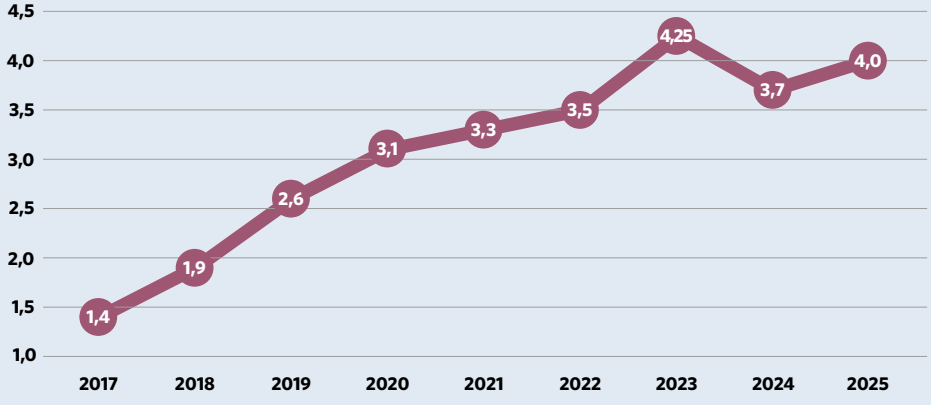
Parallel Trade

If a medicinal product is not imported or exported within the EU by the manufacturer or marketing authorisation holder, but in parallel by a third party via a distribution channel not defined by the manufacturer or marketing authorisation holder, this is referred to as parallel trade. The prices of medicinal products 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 product, which makes it attractive for parallel traders to buy them 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 labelling 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 organisations that rely on such parallel imports are usually very small, as the majority of the margin remains with the parallel trader.

Compared to 1.4 % in 2017, the share of parallel imports into Austria has risen steadily in recent years. According to IQVIA, it stood at 4 % for the total market in 2025. The extramural sector is strongly affected, with a share of 5.7 % (132). In 2024, social security additionally regulated the dispensing of parallel-imported medicinal products in pharmacies by means of a guideline, in order to prevent financial disadvantages for the healthcare system (133).

Parallel import in Austria



Figures in %

Source: IQVIA 2026

Austria is also heavily 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 Austria despite the market authorisation holder's proven ability to supply. For this reason, the Ordinance on Securing the Supply of Medicinal Products (Federal Law Gazette II No. 30/2020, (126)) created the possibility for the Federal Office for Safety in Health Care (BASG) to impose a temporary ban on parallel exports for products with distribution restrictions.

Distance Selling – Mail Order Business

Distance selling within the meaning of § 59a of the Medicinal Products Act (AMG) is the sale of prescription-free medicinal products 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, (135)), a uniform logo for labelling authorised online pharmacies was created for all EU member states and mail-order sales were thus also introduced in Austria.

When ordering from an Austrian online pharmacy, look out for the Austrian flag symbol. Internet pharmacies that operate from other EU countries can also be recognised by the respective flag symbol. Legal online pharmacies are only allowed to sell prescription-free medicinal products in or to Austria.

Since 25 June 2015, distance selling in Austria has also been possible for Austrian pharmacies. Information on all mail-order pharmacies registered in Austria can be found in the AGES medical market supervision list: versandapotheken.basg.gv.at

The legal regulations are set out in the Distance Selling Ordinance (Fernabsatzverordnung (136)).

5.6 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 authorisation holders have been required to report any restriction of the ability to distribute prescription medicinal products for human use since 1 April 2020 (134). The notifications are published in the Distribution Restriction Register on the BASG website (Medikamente Info Austria) (137). 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 substances
- 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 Section 5.5)

ures 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 (138):

- **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 Distribution Restriction Register** to the doctors' practice software
- **Regulatory flexibilities** with regard to the import (transfer) of medicinal products with foreign-language instructions.
- **Introduction of a harmonised 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), SPOR (Substances, Products, Organisations 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 organisations 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 MSSG (Medicine Shortages Steering Group of the EMA) for support when procuring stocks of the medicinal product concerned.
- **EU Critical Medicines Alliance** as a measure to prevent supply bottlenecks. The group began its work in January 2024 and will initially support the European Commission in an advisory capacity for five years. The Alliance published its first strategy report on 28 February 2025. The report sets out the key findings and recommendations for improving the safety and resilience of critical medicinal product supply chains in the EU (139).
- **European Shortages Monitoring Platform (ESMP)** to collect information on the availability and demand for medicinal products and to prevent, detect and manage shortages of medicinal products for human use in the EU and EEA (140).

- **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 realise due to global supply chains. From the point of view of companies from various industrial sectors (including the pharmaceutical industry), the main challenges 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 substances with high volume and low complexity

Changes were also made in the area of legislation to help strengthen the supply of medicinal products:

A legal obligation on marketing authorisation holders to ensure supply has existed for a long time. The Austrian **Stockpiling Ordinance,** issued in June 2024 (141), supplements this with a quantitative requirement for certain medicinal products. Since 21 April 2025, the respective marketing authorisation holder must stockpile the medicinal products listed in the annex to the ordinance in Austria. The quantity to be stored corresponds to Austria-wide demand for four months – calculated on the basis of the packs dispensed in the previous calendar year. The Stockpiling Ordinance primarily concerns prescription-only, off-patent human medicinal products that have been categorised as supply-critical within the meaning of this ordinance. The Annex to the Stockpiling Ordinance is revised regularly.

Stockpiling is intended to ensure that sufficient goods are available in Austria, even if demand suddenly increases. If a pharmaceutical company has to use up its stock, this must be reported to the BASG and the prescribed stock level must then be restored as quickly as possible. The BASG provides practical information online in the form of a guide (142) and FAQs (143). Marketing authorisation holders can generally claim reimbursement for additional costs incurred as a result of stockpiling. Details on this are regulated in § 94k AMG.

At European level, the **drafts of the new EU pharmaceutical legislation** provide for extensive rules to ensure the supply of medicinal products. Among other things, these are intended to prevent special national regulations that could lead to a deterioration in the availability of medicinal products. The aims are an efficient, coordinated approach at EU level and harmonised rules in all EU member states.

The **EU Critical Medicines Act** (currently at the draft stage) is intended to improve the availability of medicines classified as essential. To achieve this, the EU intends, among other things, to promote the production of these medicines within the EU and thus reduce dependencies on third countries. It remains to be seen which measures the EU member states will be able to agree on.

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

6.19 euros

in 2025

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

2025 +3.6 %.

6. Pharmaceutical Market

6.1 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, (144)) and the General Social Insurance Act (ASVG, for inclusion in the Reimbursement Code). The Price Commission of the Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection (BMASGPK) is responsible for setting the prices of medicinal products (145).

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

Medicinal Product Price

- **Factory/Depot Selling Price (MSP/DSP):** Manufacturer/Depositor › Wholesale
- **Pharmacy Purchase Price (PPP):** Wholesale › Pharmacy

In case of REFUND:

- **Health Insurance Price (KKP):** Pharmacy › Social Insurance Institutions

For PRIVATE PURCHASE:

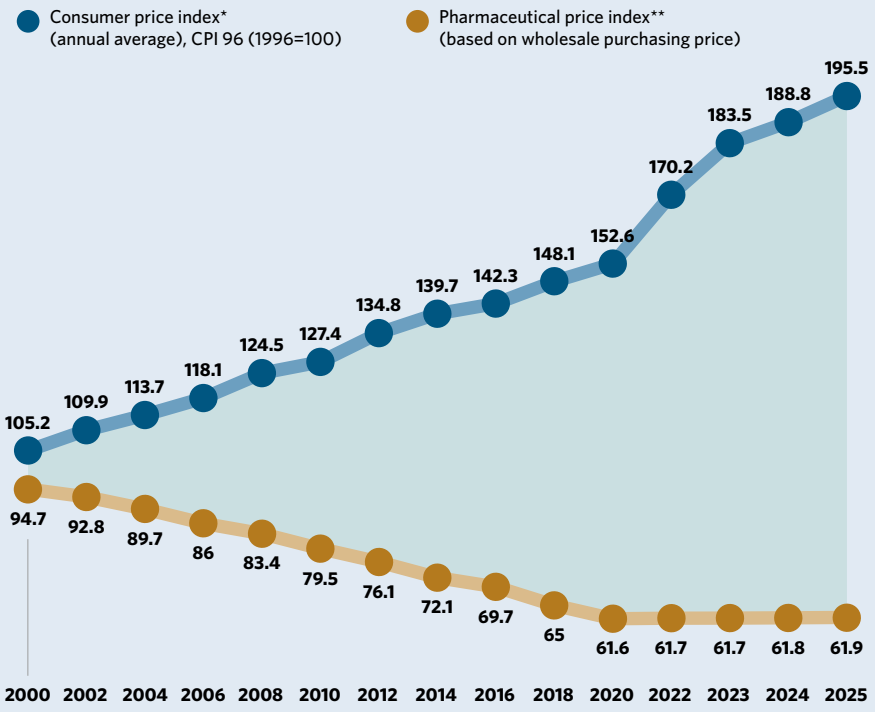
- **Pharmacy Sales Price (AVP):** Pharmacy › Private customer

Pricing Example

*Prescription fee since 1 January 2026: 7.55 euros; **VAT since 1 January 2009: 10 %

Source: PHARMIG, eigene Darstellung

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.

Source: PHARMIG; berechnet nach Angaben von STATISTIK AUSTRIA und IQVIA

The prices of medicinal products already available on the Austrian market have fallen every year since 1996 and have remained stable at a low level since 2020. A pack of medicine that cost 10 euros in 1996 only cost 6.19 euros in 2025. Due to legal regulations, automatic inflation adjustment is not permitted for medicinal products. Otherwise, the price of the fictitious medicine pack would have been 19.5 euros at the end of 2025. In 2025, the inflation rate was +3.6 % (132).

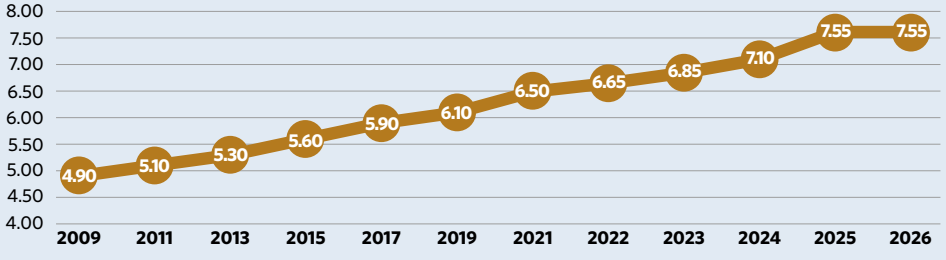
The consumer price index and the medicinal product price index diverge further from year to year. The price of medicines is falling continuously or stagnating, while the consumer price index is rising annually.

The health insurance price of around 49 % of all reimbursable* medicinal product packs (calculated by IQVIA on the basis of sales) will be below the prescription fee (7.10 euros, latest available data) in 2024 (132).

* 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 (145). In the period 2009–2026, the prescription fee rose by around 54 %. In 2025, the prescription fee meant revenue of 503 million euros for the health insurance system (provisional budget 2025) (14).

Development of prescription fees 2009–2026



Values in euros

Source: Bundeskanzleramt Österreich – Rezeptgebühren (147)

In addition to the general exemption from the prescription fee on social grounds, 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 (148).

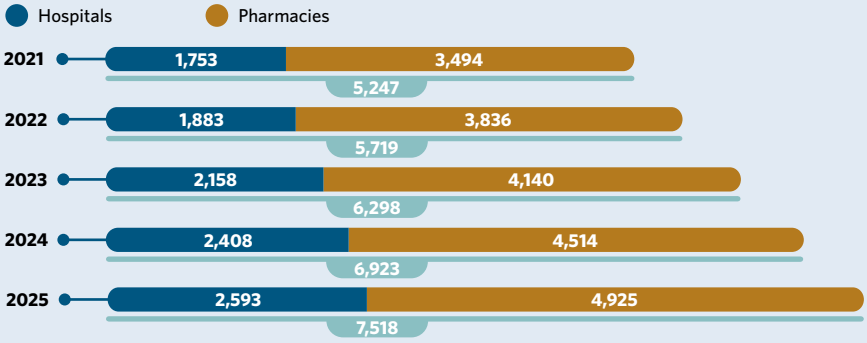
6.2 Hospital and Pharmacy Market

In 2025, the Austrian pharmaceutical market reached a value-based volume of 7.5 billion euros and a volume of 247 million packs. This represents growth of + 8.2 % in terms of sales and a marginal increase in terms of volume (132). From the perspective of manufacturers and distributors, the Austrian pharmaceutical market is divided into two segments:

- **Hospital market** (intramural sector)

Public pharmacies and **dispensing doctors** (extramural sector)

Pharmaceutical sales (based on manufacturer price, MSP*)



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

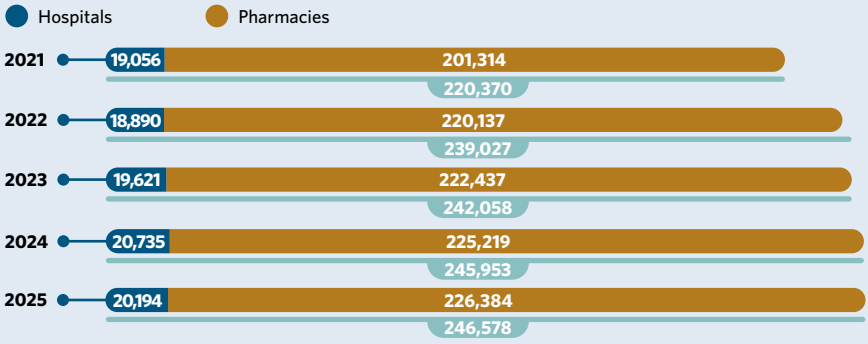
Source: IQVIA DPMÖ next level adaptierter Datenerfassung (inkl. RX Direktgeschäft) / DPMÖK

In 2025, the pharmacy market grew compared to 2024 in both value and volume, while the hospital market recorded an increase in value alongside a slight decline in volume (132).

- **Pharmacy market:** +8.6 % by value in euros in turnover and +0.2 % by volume by pack (public pharmacies).
- **Hospital market:** +7.7 % by value in euros in turnover and –2.6 % by volume by pack.

In 2025, 247 million packs were sold in Austria, 8 % of which went to hospitals (institutional pharmacies) and around 92 % to pharmacies in the extramural sector (132).

Sold packs



Figures in thousand packs

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

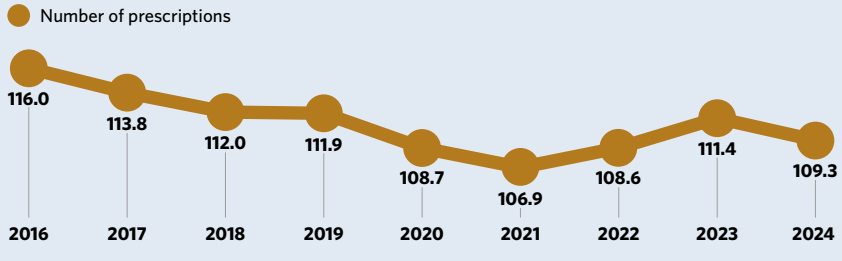
Growth in the prescription-only extramural market in 2025 was + 8.9 % (based on 2024 revenue) and, according to calculations by IQVIA, is influenced by a variety of elements (IQVIA Elements of Growth Analysis 2025):

- **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 2025, price changes have a marginal impact on market development by + 0.1 %.
- **New launches** include those products that contain new active substances in the first year after market launch. These products replace previous forms of therapy or enable new therapies for the first time. New launches had a small impact on market growth of +0.5 % in 2025 – a constant development compared to 2024.
- **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 2025, structural effects amounted to +8.4 %.

6.3 Prescription Trends

The number of prescriptions for medicinal products fell year on year over the period from 2014 to 2021. After a slight increase in 2022 and 2023, the number of prescriptions declined slightly again in 2024.

Number of Reimbursed Prescriptions

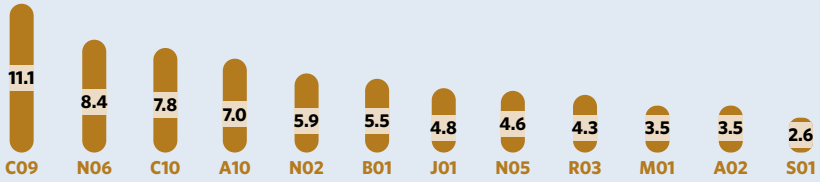


Figures in millions

Source: Die österreichische Sozialversicherung in Zahlen, März 2026 (14)

6.4 Pharmaceutical Consumption by Indication Groups

The most frequently prescribed therapeutic subgroups ATC-level 2*, 2024



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

C09 Agents acting on the renin-angiotensin system
N06 Psychoanaleptics
C10 Lipid modifying agents
A10 Drugs used in diabetes
N02 Analgesics
B01 Antithrombotic agents
J01 Antibacterials for systemic use
N05 Psycholeptics
R03 Drugs for obstructive airway diseases
M01 Anti-inflammatory and antirheumatic products
A02 Drugs for acid-related diseases
S01 Ophthalmologicals

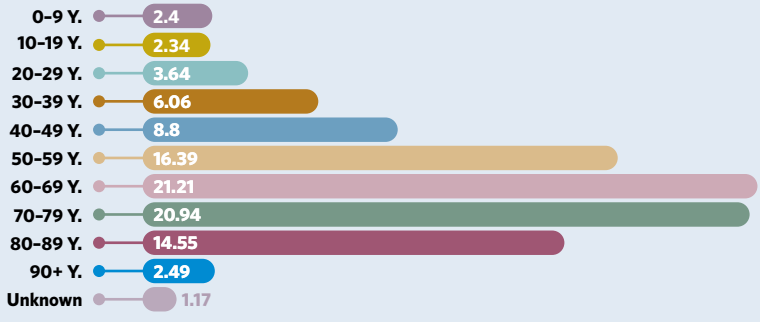
Source: Die österreichische Sozialversicherung in Zahlen, März 2026 (14)

The ten indication groups with the highest number of prescriptions account for more than 50 % of all prescriptions.

The most frequently prescribed medicinal products according to the ATC system are: agents acting on the renin-angiotensin system (e.g. for high blood pressure), psychoanaleptics (for mental illnesses, e.g. depression) and lipid modifying agents. These three therapeutic groups with the highest prescription volumes account for around 27 % of all prescriptions (14).

6.5 Pharmaceutical Requirements by Age

Pharmaceutical requirements in 2025 in %
(Patients with statutory health insurance, by packs)

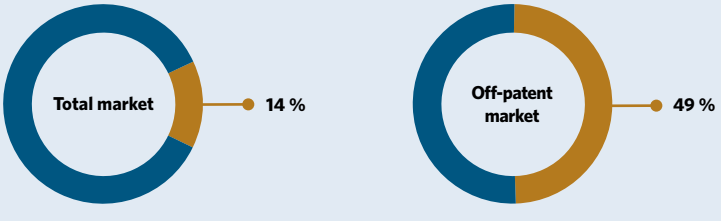


Source: Apothekerkammer Österreich (149)

The need for medicinal products also increases sharply from the age of 50. The need of all people aged 60 and over is 59.19 % (149).

6.6 Generic Medicinal Products

Generics' share of revenue in 2025



Figures in %

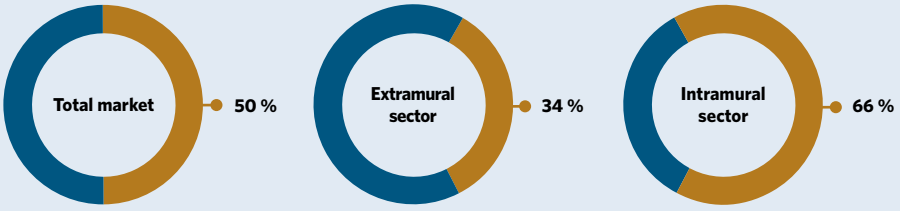
Source: Österreichischer Generikaverband – Generika-Anteile 2025 (150)

From the perspective of the Austrian social security system, the generics share of prescriptions in 2025 was 62.64 %, i.e. more than every second pack dispensed was a generic (151) (see also Sections 3.2 and 7.3).

6.7 Biosimilars

At the end of 2025, 75 authorised biosimilars (for 23 different active substances) were available in Austria for the treatment of diseases such as cancer, autoimmune diseases, growth disorders, osteoporosis or blood coagulation. The European Commission has authorised 142 biosimilars for 27 active substances (as of 12/25) (152).

Biosimilars accounted for 50% of the total possible biosimilar market in Austria (in terms of revenue) in 2025: In the extramural market, this share is around 34 % and in the hospital market 66 % (152).



Figures in %

Source: Biosimilarsverband Österreich (152)

In Austria, the generics and biosimilars price rule also results in significant price reductions for the original supplier (see Sections 3.2, 7.3).

The introduction of biosimilars and the associated price reductions of reference medicines in the retail and hospital sectors have resulted in savings of around 1.18 billion euros (MSP) over the last 14 years. A further considerable savings potential of around 330 million euros (MSP) can be realised for Austria by 2027 (consumption and price simulation study) (153).

6.8 Self-medication Market

The OTC market grew by + 8 % in value terms in 2024 compared to 2023 to 1.541 billion euros (AVP). The average revenue growth since 2022 is 5.3 % per year. The increase in 2025 was significantly below this. In terms of volume, after a decline of 0.3 % in 2023 and 0.5 % in 2024, a decline of 3 % was recorded in 2025. (154).

Drugs for the treatment of coughs and colds continued to be the largest indication group in 2025 with a share of 23.7 % (measured in terms of sales in AVP), however with a falling trend. In this indication group, drugs for the treatment of coughs saw the largest decline in 2025 while the sale of products for the treatment of flu and cold symptoms increased. The top-growing category in 2025 was vitamins, minerals and food supplements, with a sales increase of 5.8 % (154).

Indication groups in self-medication (basis AVP) 2025

Figures in %

Source: IGEPHA Jahresbericht 2025 (154)

Medicinal products for self-medication, so-called "over the counter" (OTC) medicines, are effective, safe and make sense in terms of healthcare economics. They are therefore an integral part of healthcare and the treatment of many illnesses. Around one in four medicinal products dispensed in pharmacies in Austria is an OTC medicine.

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 are convincing in terms of their

Benefits and costs.

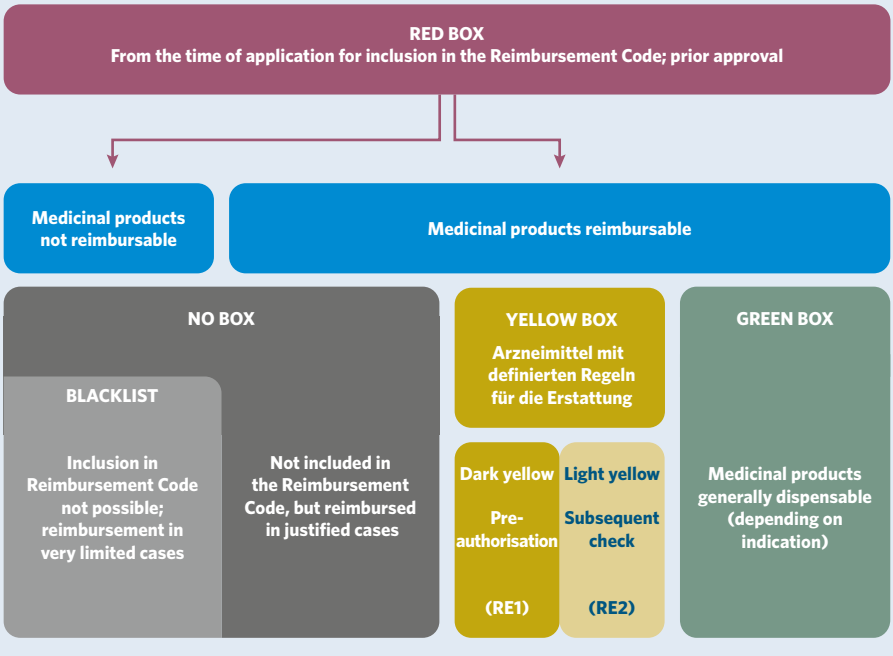
7. Reimbursement of Pharmaceuticals by Social Security

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 appropriate but must not exceed what is necessary." (§ 133 ASVG)

7.1 The Reimbursement Code (EKO)

The ASVG regulates access to medicinal products for all insured people in Austria after approval by the social security system. The Reimbursement Code (EKO), which is published by the umbrella association of the Austrian social security institutions, 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 Section 7.2). 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 (155).

The box system – simplified presentation



Source: FOPI – Erstattungskodex (EKO) und Arzneimittel-"Boxensystem" (156)
Der EKO gliedert sich in drei Bereiche (auch Boxen genannt) (153).

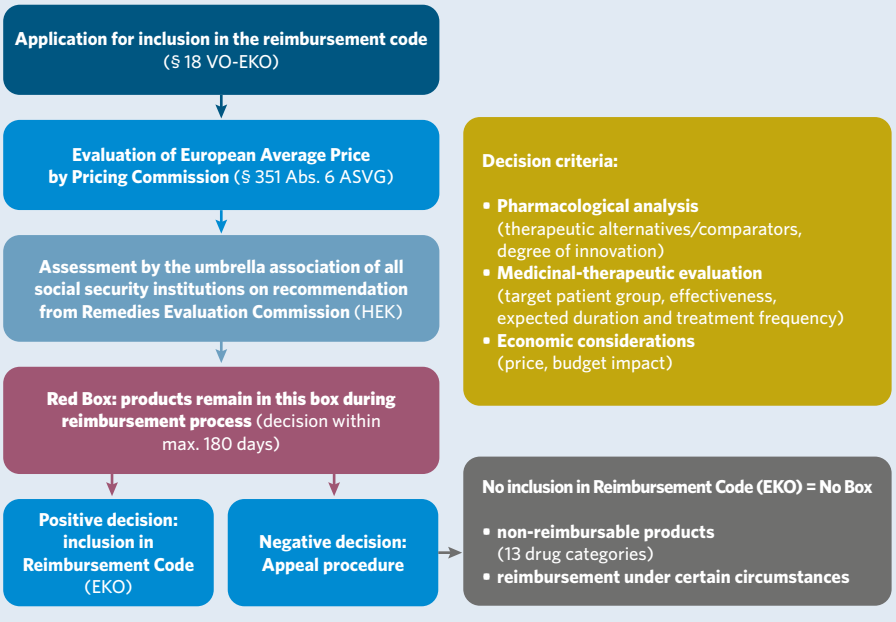
The EKO is divided into three areas (also called boxes) (157):

- **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 authorisation of a chief consultant (control physician) belonging to the health insurance is not required if the rules of the EKO are complied with. The comparator products listed in this area are decisive for price fixing. If a higher price is sought for the speciality 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 authorisation 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 association of the social security institutions 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 speciality 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 approval has been obtained. Authorisation must be granted via the Medicinal Products Licensing Service ABS.

Application for Inclusion in the Reimbursement Process (VO-EKO according to § 351 ASVG)

On the basis of the ASVG (158) (§ 351c ff.), the Rules of Procedure for the Publication of the Reimbursement Code (VO-EKO, (159)) 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 (160), and the monthly changes are published on the internet under www.ris.bka.gv.at (161).



Source: Österreichische Gesundheitskasse, Arbeitsbehelf Erstattungskodex (162)

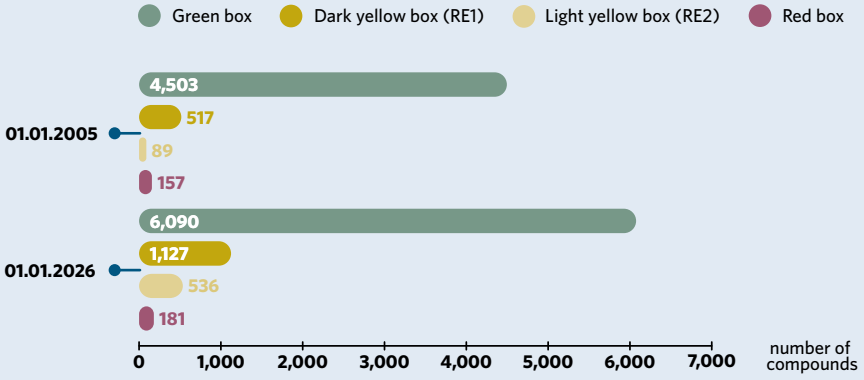
Certain groups of medicinal products are generally excluded from inclusion in the EKO (Official Announcement No. 34/2004; list of non-reimbursable categories of medicines in accordance with § 351c (2) ASVG) and must usually be paid for by the patients themselves, unless the assumption of costs has been approved in advance by the chief medical service (e.g. medicines that are mainly dispensed in hospitals, contraceptives, etc.). (162).

Remedies Evaluation Commission (HEK)

The Remedies Evaluation Commission is the advisory body of the umbrella association of all social insurance institutions (DVSV). All applications for the inclusion (including changes) of a speciality medicinal product in the Reimbursement Code must be submitted to the HEK. The HEK must also be consulted if the DVSV intends to make a change to the Reimbursement Code on its own initiative. The HEK shall submit a written recommendation to the DVSV (163).

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

Number of medicinal products in the EKO as per 1 January 2026*



The data was taken from the list of goods published by the Austrian Pharmacists Publishing House | as of 1 January 2026
*by the package – pharmaceutical registration numbers

Source: Dachverband der Sozialversicherungsträger (164)

As of 1 January 2026, a total of 7,934 packs were listed in the EKO, compared to 5,266 packs when it was introduced in 2005 (164).

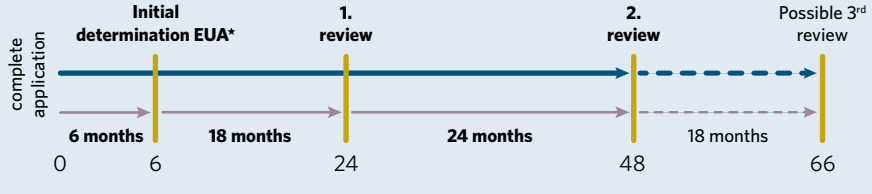
7.2 Specific Price Regulations Through Social Insurance

EU Average Price

As part of the 61st ASVG amendment, the EU average price (165) was newly regulated as the maximum limit for reimbursement prices. The Price Commission of the Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection determines the EU average price from the prices reported by the companies in the EU member states.

As long as the EU average price cannot be determined, the price reported by the authorised distributor applies provisionally (the EU average price can be determined if the factory or depot selling price (MSP/DSP) is available in at least two EU member states other than Austria). 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 consulted for this purpose. After the initial price determination, the price commission must determine an EU average price after 18 months and again after a further 24 months; a new determination is possible after a further 18 months.

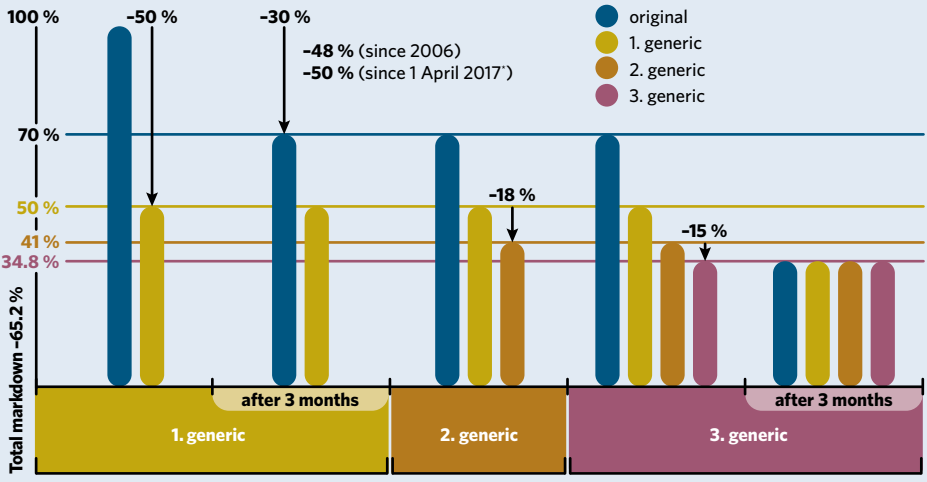


*EUA= EU average price

Source: Österreichische Gesundheitskasse – Arbeitsbehelf Erstattungskodex (162)

Generic Medicinal Products

The 2017 amendment to the ASVG (BGBl. I 49/2017) amended the previous price regulation for the inclusion or retention of interchangeable products with the same active substance (original and successor products) (Section 351c (10) (1) ASVG, for generics see also Section 3.2).

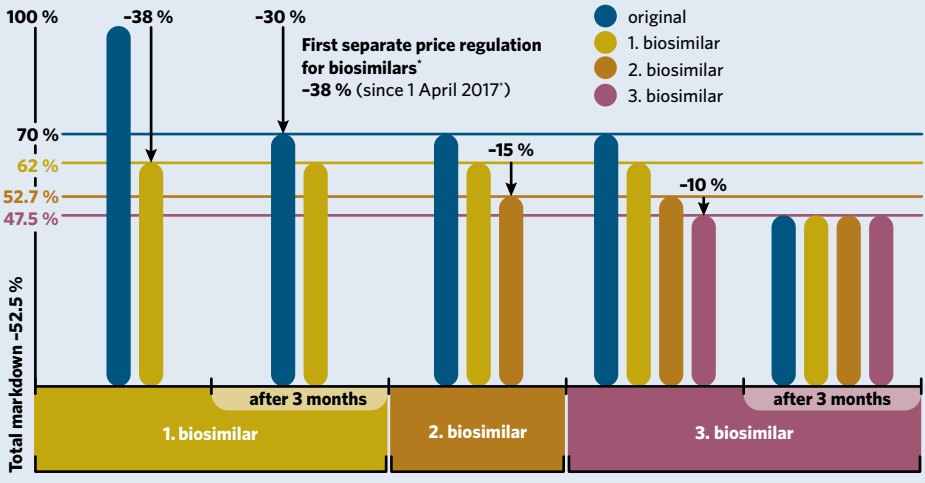


*ASVG amendment from BGBl. No. I, 49/2017 § 351c Para. 10 in force as of 1 April 2017, limited until 31 December 2029

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 Section 3.2), which makes it easier to plan market entry.



*ASVG amendment from BGBl. No. I, 49/2017 § 351c Para. 10 in force as of 1 April 2017, limited until 31 December 2029 (BGBl. No. 106/2025)

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

Price Range

Due to price divergences of individual active substances within the green box, a price range alignment is scheduled every two years since 2017. The price of the affected speciality medicinal products with the same active substance (see the respective announcement of the then umbrella association) in the green box may not exceed 30 %, or 20% since 2023, above the price of the cheapest speciality medicinal product of the same active substance on the reference date (1 February of the review year) (2017 amendment to the ASVG, § 351c para. 11). The key strength (the one most frequently prescribed) is decisive for calculating the price range within an active substance. A price reduction is only required down to the level of the prescription fee, i.e. speciality medicinal products whose price is below the prescription fee are exempt from this rule. However, these are used to determine the maximum price. The price has to be lowered accordingly in October of that year. In return, cancellation procedures for these products are omitted for economic reasons until the end of that year (159).

A new implementation of the price range in 2025 for the years 2027 and 2029 was decided with the 2023 amendment to the ASVG (BGBl. 106/2025).

According to the social insurance organisation, the savings from the price range in 2017, 2019 and 2021 amounted to around 74 million euros. According to IQVIA's calculations, social insurance can expect savings of more than 90 million euros for 2023 (based on Health insurance provider sales price (KVP), list prices, sources: Parliamentary enquiry response 8908/AB, IQVIA).

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 speciality medicinal products that are not listed in the EKO (see Section 7.1), 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 MSP offset against social security exceeds the EU average price, there is an obligation to repay these speciality medicinal products in excess of the difference (162).

Price Increases

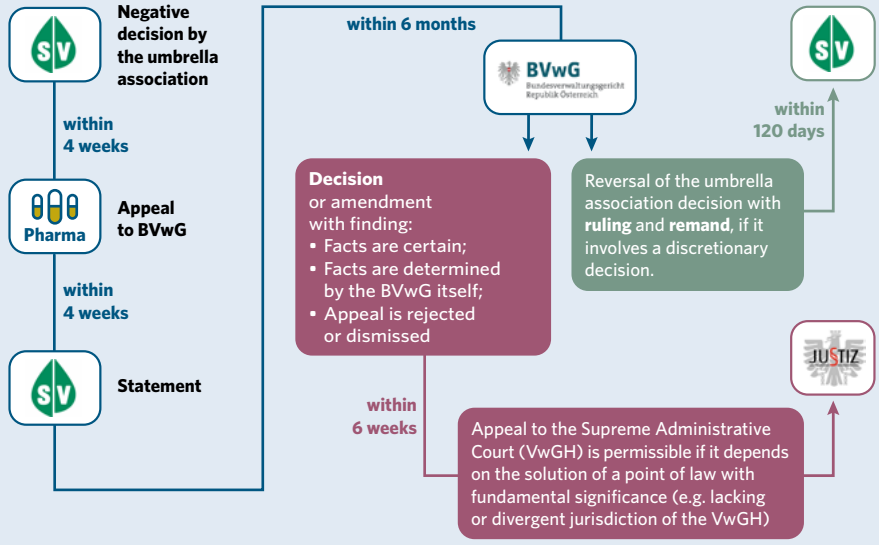
Price increases for medicinal products are regulated by law in a very restrictive manner (e.g. max. every 24 months) and are only possible to a very limited extent. The umbrella association has a wide margin of discretion in this regard (162).

7.3 Federal Administrative Court

The Federal Administrative Court (BVwG) is responsible for appeals against a decision of the umbrella association 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) (166).

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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High

Ethical Standards

are a cornerstone of the pharmaceutical industry.

Starting with research and new ways of utilising data, through production along the entire supply chain of medicinal products to their marketing.

Voluntary

self-regulation, transparency and measures for a fair contribution to greater sustainability reinforce this.

8. Compliance | Ethics | Sustainability

Pharmaceutical companies develop, produce and sell medicinal products. From research and production to dispensing to patients – high ethical standards and integrity must be maintained along the entire supply chain. Industry-wide, voluntary codes of conduct and internal company compliance standards contribute significantly to the trust of partners in the healthcare sector and the public in the values of the pharmaceutical industry. They demonstrate a great sense of responsibility and the clear will of PHARMIG member companies to live a high-quality industry culture.

8.1 Compliance

Compliance refers to acting in a legally and ethically correct manner. Compliance requirements concretise legal obligations or sometimes go beyond them. For the pharmaceutical industry, a key element of this is international voluntary self-regulation. Based on the global IFPMA Code of Practice (167) and the European EFPIA Code of Practice (168), the Austrian PHARMIG Code of Conduct (CoC) provides a sensible basis for practical aspects of cooperation with healthcare professionals (e.g. doctors, pharmacists), healthcare organisations (e.g. hospitals, medical societies) and patient organisations since 1970.

8.1.1 The PHARMIG Code of Conduct (CoC)

It is also part of the responsibility of pharmaceutical companies to inform doctors, pharmacists, patients and the general public about their products and thus contribute to their correct use and pharmaceutical safety. The exchange of experience is an essential aspect of this, which also flows into the further development of therapy concepts. The focus is on the scientific context as well as the traceability and transparency of the collaboration.

The aim of the CoC is to protect the procurement, decision-making and therapeutic freedom of healthcare professionals from unfair influence as well as the independence of patient organisations and thus ultimately to ensure the best possible medical care and treatment for patients. In addition, the CoC promotes fair competition within the pharmaceutical industry.

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 a so-called CoC procedure. A flow chart and more information on the PHARMIG Code of Conduct can be found on our website (169).

8.1.2 Transparency Creates Trust

Since 2014, the CoC also contains provisions on how pharmaceutical companies disclose non-cash benefits, for example when they collaborate with doctors or hospitals or support the work of patient organisations. You can find more information on the transparency initiative on our website (170).

8.2 Ethics

In addition to maintaining high ethical standards in the area of information about medicinal products and cooperation with healthcare professionals, healthcare organisations and patient organisations, the constantly growing possibility of data use in particular poses new ethical challenges.

The use of existing data for other purposes has great potential, for example for research, product strategies or to underpin presentations. But is everything that is legally permitted also ethically justifiable? The sensitive issue of utilising patient data in particular requires the utmost sensitivity and integrity. It is important to create a framework for the secure, responsible handling of data and to use high ethical standards to allay fears of the transparent individual. Internal company regulations should ensure this. Association-wide guidelines support this.

This is precisely where the **European Health Data Space (EHDS)** comes in. This first common EU data space is intended to enable the secure exchange of health-related data. This can improve healthcare and, under certain conditions, facilitate and advance research. The corresponding EU regulation (68) came into force on 26 March 2025. The regulations relevant to the practical use of the EHDS will apply from March 2029. Further information on this can be found in our press release "European Health Data Space opens up new opportunities for citizens, research and health policy" from 7 March 2025 (171) (see also Section 2.6).

Another challenge is the use of **artificial intelligence (AI).** With the AI Act (172), the EU has created the world's first legal framework for the use of AI. The rules are due to apply from August 2026. For pharmaceutical companies, AI offers new opportunities, from clinical research to the marketing of medicinal products. Here too, the challenge is to master the tension between theoretical potential and ethically justifiable use. Particularly in view of the rapid development of AI, reflection on ethical principles is highly relevant.

8.3 Sustainability

Various aspects of sustainability, e.g. in the area of environmental protection or fair production conditions, are also a key issue in the pharmaceutical industry. The CO_2 footprint is inevitably large, the supply chains are global and also include countries whose labour law and environmental protection requirements do not correspond to those in Europe.

How can the balancing act between high sustainability standards and at the same time ensuring the supply of medicinal products at the usual low prices be achieved in the best possible way?

Wherever possible, pharmaceutical companies are switching production and packaging facilities to more environmentally friendly technologies and using electricity from renewable energy sources. In addition, they are increasingly focussing on sustainable office buildings with energy supply from wastewater heat and solar energy.

Other measures include reducing air travel, introducing an annual CO_2 budget and incentivising the use of public transport.

The distribution of medicinal products is increasingly focussing on electromobility. More and more online information is being used to market products, as this has to be constantly updated anyway.

The European Union (EU) is attempting to ensure a high level of sustainability through mandatory reporting obligations for companies along the supply chain and various legal projects.

These include:
- Corporate Sustainability Reporting Directive (CSRD) (173)
- Corporate Sustainability Due Diligence Directive (CSDDD) (174)
- Regulation on fluorinated greenhouse gases (F-Gas Regulation) (175)
- Packaging and Packaging Waste Regulation (PPWR) (176)

Furthermore, several national authorities submitted a proposal to the European Chemicals Agency (ECHA) to restrict per- and polyfluorinated alkyl substances (PFAS) within the framework of REACH (177), the EU's so-called chemicals regulation (178). The ECHA has not yet made a decision.

8.3.1 Urban Waste Water Treatment Directive (UWWTD)

The European Commission wants to achieve a pollution-free environment by 2050 by improving air, soil and water quality. In the wastewater sector, micro-pollutants are to be removed from wastewater by introducing a fourth purification stage, among other things.

The associated directive on the treatment of urban wastewater (KARL, UWWTD) (179) establishes extended producer responsibility and applies the polluter-pays principle. The underlying intention is to achieve a steering effect and to reduce the use of substances that have a negative impact on the environment or to substitute them with other substances. Accordingly, those industrial sectors that cause micropollutants should bear the costs for the expansion and operation of the fourth treatment stage at municipal wastewater treatment plants. The European Commission sees two sectors as being responsible here: manufacturers of medicinal products for human use and cosmetics; whereby the directive defines "manufacturer" as "any producer, importer or distributor who places products on the market in an EU member state, including by means of distance contracts" (Art. 2). The directive also provides exemptions for manufacturers who only place small quantities of a substance on the market in the European Union (< 1 tonne/year) or who can prove that no micropollutants are produced at the end of a product's life or that the residues are rapidly biodegradable.

There are no plans to introduce the fourth treatment stage across the board. The directive is based on size criteria (plants with a population equivalent of more than 150,000) and a risk-based approach (plants with a population equivalent of more than 10,000 in a so-called risk area). Only estimates are currently available with regard to the exact number of wastewater treatment plants affected and, consequently, the amount of the concrete costs to be expected.

According to the directive, the affected sectors will have to bear at least 80% of the costs (up to 20% can be financed from public funds in accordance with the directive) for the expansion and operation of the fourth treatment stage from the end of 2028. An evaluation of the directive is planned for 2033, which will make it possible to extend the payment obligation to other sectors that cause micropollutants.

The directive came into force on 1 January 2025. The Federal Ministry of Agriculture, Forestry, Climate and Environmental Protection, Regions and Water Management is already working on the transposition of the directive into national law, which must take place by 1 July 2027.

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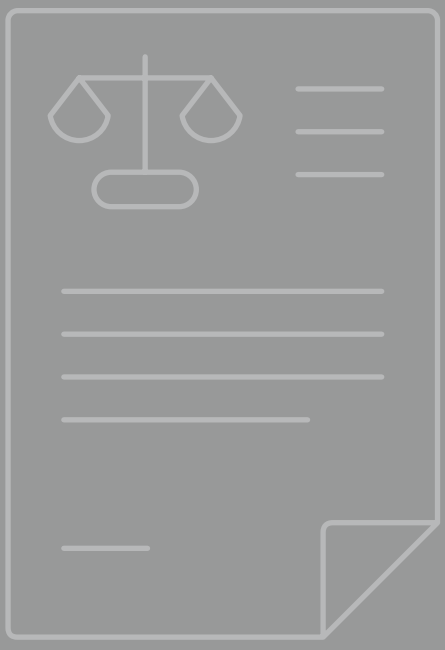


9. Laws and Regulations

The most important legal and other regulations that apply to the development, manufacturing, testing, authorisation and distribution of medicinal products. More information on national and EU legislation can be found at www.pharmig.at

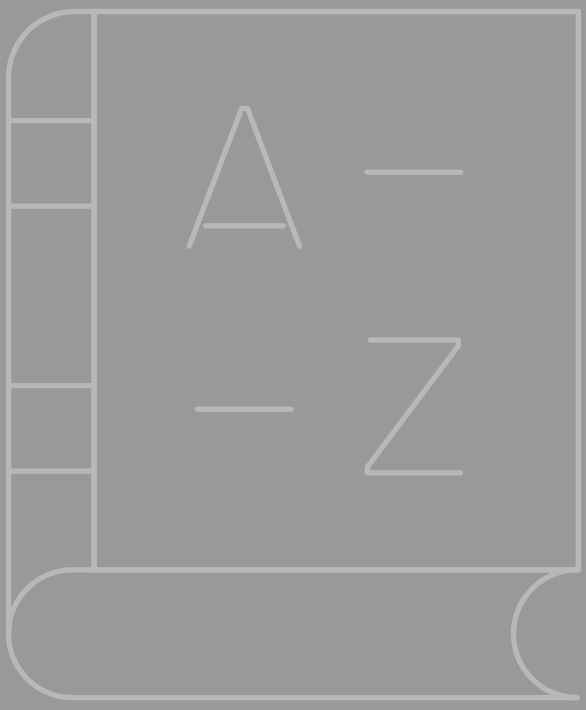
Law	Regulatory Areas
Legal Requirements in Austria	
General Social Insurance Act **(Allgemeines Sozialversicherungs-gesetz – ASVG)**	General social insurance for people employed in Austria, including self-employed people of equal status, and health insurance for pensioners from the general social insurance scheme; general social insurance includes health insurance, accident insurance and pension insurance with the exception of certain special insurance schemes.
Medicinal Products Act **(Arzneimittelgesetz – AMG)**	Definitions, clinical trials, marketing authorisation, manufacture, distribution, advertising, pharmacovigilance, approval of plant and equipment
Federal Act on the Import and Movement of Medicinal Products, Blood Products and Products from Natural Medicinal Resources **(Arzneiwareneinfuhrgesetz 2010 – AWEG 2010)**	Import and transfer of medicinal products
Federal Act on the Award of Contracts **(Bundesvergabegesetz 2018 – BVergG 2018)**	Procedure for the procurement of services (award procedure) in the public sector
Federal Act on Hospitals and Health Resorts **(Bundesgesetz über Krankenanstalten und Kuranstalten – KAKuG)**	Basic provisions on hospitals
Federal law that lays down provisions on prices for goods and services **(Preisgesetz 1992)**	Price fixing for goods and services and (by ordinance) maximum mark-ups (margins)
Federal Act on the Supply of Medicinal Products and Veterinary Medicinal Products on the Basis of a Medical or Veterinary Prescription **(Rezeptpflichtgesetz – RezeptPG)**	Prescription status of human and veterinary medicinal products

Law	Regulatory Areas
Federal Constitutional Law **(Bundes-Verfassungsgesetz – B-VG)**	Basic structure of the Austrian constitution: including four basic principles, division of competences between the federal government and the provinces
Health and Food Safety Act **(Gesundheits- und Ernährungssicherheitsgesetz – GESG)**	Outsourcing of tasks and processes relating to medicinal products and medical devices from the BMASGPK to the AGES Medical Market Supervisory Authority
Rules of procedure for issuing the Reimbursement Code pursuant to Section 351g ASVG **(VO-EKO)**	Regulation issued by the umbrella association of social security institutions: Application for inclusion in the reimbursement process
Ordinance on establishments that manufacture, control or place medicinal products or active substances on the market and on the brokering of medicinal products **(Arzneimittelbetriebsordnung 2009 – AMBO 2009)**	Good manufacturing practice, good distribution practice, pharmaceutical quality assurance
Ordinance on the Stockpiling of Speciality Medicinal Products for Human Use **(BevorratungsVO)**	Stockpiling of the human medicinal specialities listed in the Annex to the Ordinance in sufficient quantities in Austria
Ordinance on the sale of human medicinal specialties via distance selling **(Fernabsatz-Verordnung)**	Mail-order of medicinal specialties
Regulation of prescription-only medicinal products **(Rezeptpflichtverordnung)**	Restrictions on the supply of the medicinal products listed in the Annex to the Regulation
Ordinance on the safeguarding of the supply of medicinal products	Obligation to notify a restriction on the ability to distribute prescription-only medicinal products for human use; distribution restriction register

Law	Regulatory Areas
EU Laws	
Delegated Regulation (EU) 2016/161 laying down detailed rules for the **safety features** appearing on the packaging of medicinal products for human use	Safety features on the packaging of medicinal products for human use.
Directive 2001/83/EC in order to establish a **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 Medicinal Products Act
Directive 2011/62/EU on the **prevention** of the **entry of falsified** medicinal products into the legal supply chain **(Fälschungsrichtlinie)**	Prevention of the entry of falsified medicinal products into the legal supply chain
Regulation (EU) 2019/1937 Corporate **Sustainability** Due Diligence Directive **(CSDDD)**	EU Supply Chain Directive - Corporate due diligence in the areas of human rights and environmental protection along the value chain
Regulation (EU) 2022/2464 Corporate **Sustainability Reporting** Directive **(CSRD)**	Reporting in accordance with the European Sustainability Reporting Standards (ESRS)
Regulation (EU) 2024/3019 Urban Waste Water Treatment Directive **(KARL, UWWTD)**	Avoidance of negative impacts from insufficiently treated wastewater; Introduction of a 4th filtration stage in wastewater treatment plants
Regulation (EC) No 141/2000 on **Orphan Medicinal Products**	Special rules for medicinal products for rare diseases (Rare Diseases)
Regulation (EU) No 536/2014 on **clinical trials** on medicinal products for human use	EU-wide regulations for clinical trials on medicinal products for human use

Law	Regulatory Areas
Regulation (EC) No 726/2004 laying down Community procedures for the **authorisation** and **supervision** of **medicinal products for human use** and establishing a European Medicines Agency	Central authorisation of medicinal products in the EU, establishment of the EMA
Regulation (EC) No 1901/2006 on medicinal products for **paediatric use**	Rules for the development of medicinal products for human use where a specific therapeutic need in the paediatric population is to be covered without unnecessary clinical or other trials
Regulation (EC) No 1394/2007 on **advanced therapy medicinal products**	Legal framework for gene therapy products, somatic cell therapy products and biotechnologically processed tissue products
Regulation (EU) 2021/2282 on health technology assessment **(HTA Regulation)**	Evidence base for the assessment of new health technologies
Regulation (EU) 2024/573 on fluorinated greenhouse gases **(F-Gas Regulation)**	Reduction of the availability of particularly climate-damaging partially fluorinated hydrocarbons
Regulation (EU) 2025/40 on Packaging and Packaging Waste **(PPWR)**	Requirements for the entire life cycle of packaging regarding its ecological sustainability and labelling
Regulation (EC) 1907/2006 **(REACH Regulation)**	Safety of chemicals/PFAS
Regulation (EU) 2025/327 on the European Health Data Space **(EHDS)**	Establishment of the European Health Data Space (EHDS)

Other Regulations		Regulatory Areas
Good Distribution Practices	GDP	Guidelines for medicinal product storage and transport
Good Manufacturing Practices/ EU GMP Guide	GMP	Guidelines for the quality assurance of production processes and the production environment in the manufacture of medicinal products and active substances
Good Pharmacovigilance Practices	GVP	Guidelines on the post-authorisation safety monitoring of medicinal products
Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products		Requirements for risk assessment and mitigation before the first administration of an investigational medicinal product in humans and in early clinical trials
EFPIA Code of Practice		Ethical rules agreed to by EFPIA members for the advertising of medicinal products to healthcare professionals
ICH Guidelines		International scientific and technical harmonisation recommendations on the quality, safety and efficacy of medicinal products throughout their entire life cycle
IFPMA Code of Practice		Framework for compliance with regulations for clinical research, fees for services, support for medical training
PHARMIC Code of Conduct	CoC	Regulations for the information and advertising behaviour of pharmaceutical companies and the cooperation with professionals and institutions from the medical community as well as patient organisations
PIC/S		International association of medicines inspectorates that promotes the harmonisation and mutual recognition of GMP inspections



10. Abbreviations

ADCs	Antibody-Drug Conjugates
AEP/PPP	Pharmacy Purchase Price
AGES	Austrian Agency for Health and Food Safety
AI	Artificial Intelligence
AMBO	Ordinance on Pharmaceutical Establishments
AMDC	Austrian Micro Data Center
AMG	Medicinal Products Act
AMR	Antimicrobial Resistances
AMVO	Austrian Medicines Verification Organisation
AMVS	Austrian Medicines Verification System
ASVG	General Social Insurance Act
ATC	Anatomical-Therapeutic-Chemical Classification System
ATMP	Advanced Therapy Medicinal Products
AUVA	General Accident Insurance Institution
AVP	Pharmacy Sales Price
AwEG	Medicinal Products Import Act
B-VG	Federal Constitutional Law
BASG	Federal Office for Safety in Health Care
BGBl	Federal Law Gazette
BMASGPK	Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection
BVAEB	Insurance Institution for Public Employees, Railways and Mining
BVerG	Federal Procurement Act
BVwG	Federal Administrative Court
cGMP	current Good Manufacturing Practice
CHMP	Committee for Medicinal Products for Human Use
COVID	Corona Virus Disease
CSDDD	Corporate Sustainability Due Diligence Directive
CSRD	Corporate Sustainability Reporting Directive
CTCG	Clinical Trials Coordination Group
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation
DAP/DSP	Depot Sales Price
DCP	Decentralised procedure
DPMÖ	Umbrella Organisation of Austrian Patient Organisations
DPMÖK	Umbrella Organisation of Austrian Patient Organisations – Children
DVSV	Umbrella organisation of social insurance institutions
EC	European Commission
ECHA	European Chemicals Agency
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHDS	European Health Data Space
EKO	Reimbursement Code
EMA	European Medicines Agency

EMVS	European Medicines Verification System
ESMP	European Shortages Monitoring Platform
ESRS	European Sustainability Reporting Standards
EU	European Union
EUD/EUAP	EU Average Price
EWR/EEA	European Economic Area
F&E/R&D	Research & Development
FAP/MSP	Manufacturer Sales Price
FDA	U.S. Food and Drug Administration
FSME/TBE	Tick-borne encephalitis
FTE	Full Time Equivalent
GDP	Gross Domestic Product/Good Distribution Practices
GESG	Health and Food Safety Act
GMP	Good Manufacturing Practice
GVP	Good Pharmacovigilance Practices
GÖG	Health Austria Company (Gesundheit Österreich GmbH)
HEK	Remedies Evaluation Commission
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HTA	Health Technology Assessment
ICH	International Council for Harmonisation
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGEPHA	Interest group of Austrian remedy manufacturers and depositors
IHS	Institute for Advanced Studies
IP	Intellectual property
IPF	Institute for Pharmacoeconomic Research
IQVIA	IQVIA Market Research GmbH
IRIS	Integrated Review of Infrastructure for Safety
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
KAKuG	Hospitals and Health Resorts Act
KARL/UWWTD	Urban Waste Water Treatment Directive
KFA	Health care centre
KKP/RP	Health insurance price
KMU/SME	Small and medium-sized enterprises
KVP	Health insurance provider sales price
LKF	Performance-oriented hospital financing
MA	Marketing Authorisation
MEA	Pharmaceutical Market Regulation
MedGeF	Medication for joint financing
MMR	Measles Mumps Rubella
mRNA	Messenger Ribonucleic Acid

MRP	Mutual recognition procedure
MSSG	Medicine Shortages Steering Group
NAP.se	National action plan for rare diseases
NIH	U.S. National Institutes of Health
NIS	Non-interventional study
NKSE	National Coordination Centre for Rare Diseases
OD	Orphan Drugs
OECD	Organisation for Economic Co-operation and Development
OTC	Over The Counter
PAS	Post-Authorisation Study
PASS	Post-authorisation safety study
PFAS	Per- and polyfluorinated alkyl substances
PHAGO	Association of Austrian Wholesalers of Medicinal Products
PhRMA	Pharmaceutical Research and Manufacturers of America
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric Investigation Plan
PPWR	Ordinance on Packaging and Packaging Waste
PRAC	Pharmacovigilance Risk Assessment Committee
PVA	Pension insurance institution
PVE	Primary care unit
PwC	PricewaterhouseCoopers
QP	Qualified Person
RD	Rare Diseases
RDP	Regulatory Data Protection
RE1	Research Expenditure Type 1
RE2	Research Expenditure Type 2
RIS	Legal Information System
RL	Richtlinie/Guideline
RSV	Human respiratory syncytial virus
RX	Prescription only medicine
SARS-CoV-2	Severe acute respiratory syndrome corona-virus type 2
SHA	System of Health Accounts
SPC	Supplementary Protection Certificate
SPOR	Substances, Products, Organisations and Referentials Management Service
SV	Social security
SVS	Social insurance institution for the self-employed
USD	US-Dollar
USt.	Value added tax
UWWTD	Urban Waste Water Directive
VHC/CoC	PHARMIG Code of Conduct
VO	Regulation

VO-EKO	Rules of procedure for issuing the Reimbursement Code pursuant to Section 351g ASVG
VPI/CPI	Consumer Price Index
VwGH	Administrative Court
WHO	World Health Organization
WifOR	Economic Research Institute
WIPO	World Intellectual Property Organization
ZVR	Central Register of Associations
ÖCPA	Austrian Generic Medicines Association
ÖGK	Austrian Health Insurance Fund
ÖVIH	Austrian Association of Vaccine Manufacturers

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