Facts & Figures

2025 Edition

PHARMIG

Association of the Austrian Pharmaceutical Industry

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Imprint

Owned and Published by
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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 in parentheses or with quotation marks

202425021
PRINTED IN AUSTRIA

PEFC-zertifiziert
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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. 18,000 employees, covering around 95 % of the domestic pharmaceutical market.

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

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

As a 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!

In an era where health policy, societal and technological frameworks are constantly changing, reliable information is more important than ever. It creates order, enables factual discussion and forms the basis for sustainable decisions.

With the 2025 Edition of Facts & Figures, we aim to once again offer you a well-founded overview of the Austrian healthcare system and pharmaceutical supply. In doing so, we address current developments as well as long-term trends, that shape Austria.

Our goal with this publication is to foster a fact-based dialogue – between politics, management, research, industry, healthcare professions and the public. Because only through collaboration can the challenges of the present be overcome, and the course be set for a healthy future.

For this edition, we have not only comprehensively updated all statistical data but also streamlined the content overall. Chapter 3 now provides a concise and clear overview of the topic of pharmaceuticals. It covers the areas of manufacturing, approval and evaluation and addresses highly innovative areas. Chapter 5, which gives an overview of the pharmaceutical industry as an economic factor, has also been reworked. Lastly, chapter 8 has also been redesigned and is now titled "Compliance, Ethics, and Sustainability".

The complete Facts & Figures 2025 as well as selected graphics and the German version "Daten & Fakten 2025" 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 2025!

Kind regards,

Mag. Alexander Herzog
Secretary General, PHARMIG

approx. 55.2 billion

Euros were spent on healthcare in 2023
(equivalent to approx. 11.7 % of the national GDP)

76.6 % public

vs. 23.4 % private expenditure
(financing of the healthcare system)

1. Healthcare System in Austria

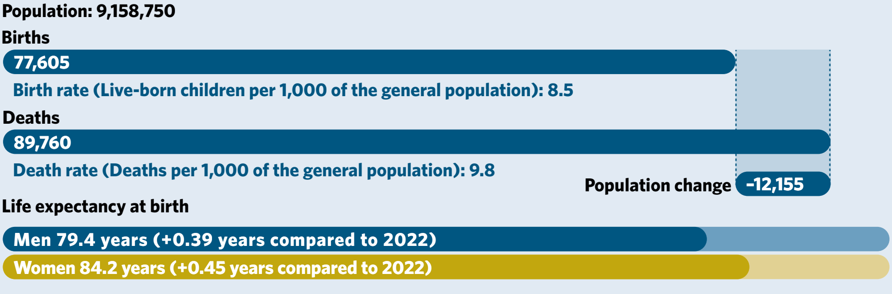
The Austrian healthcare system is characterised by the country's federalist structure. Due to the large number of decision-makers (federal, state, local, social security), the financing of healthcare is not centrally regulated and comes from various sources (such as taxes, social security contributions 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 2024, Austria's resident population numbered 9,158,750 people, 53,978 (+0.6%) more than at the beginning of 2023. This increase in 2023 can again be traced back solely to immigration (1).

Demographic Indicators of Austria

Reporting year 2023



Source: STATISTIK AUSTRIA, Demographische Querschnittsindikatoren; Demographisches Jahrbuch (2, 3)

1.2 Social Expenditure

Social Indicators of Austria	2022	2023
Gross domestic product (GDP) in billion euros	448.01	473.23
Social spending* in billion euros	136.4	146.2
Social benefits in billion euros	132.6	142.0
of which: old-age benefits, in %	44.6	45.4
of which: sickness/healthcare, in %	28.2	28.1
Share of social benefits	30.5	30.9

Source: STATISTIK AUSTRIA; Sozialquote, Sozialausgaben und Finanzierung; Bruttoinlandsprodukt (4, 5)

*Social spending: Total expenditure on social benefits, administrative costs and other expenditure (e.g. interest)

In 2023, social spending in Austria amounted to 146.2 billion euros. Almost three-quarters of this was spent on age-related and healthcare benefits. The increase in spending compared to 2022 (+7.1 %) is mainly due to above-average allocations to other social benefits in retirement (64.5 billion euros, +9.1 %) and to healthcare (39.9 billion euros, +6.6 %). The social ratio (share of social expenditure in nominal gross domestic product (GDP)) amounted to 30.9 % in 2023 and rose by 0.4 % compared to 2022 (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 2023, total healthcare spending in Austria amounted to 55.2 billion euros, which corresponds to 11.7 % of the GDP. The ongoing health expenditure (without investments) is estimated at 52.8 billion euros in 2023. With a share of 11.2 %, it lays slightly over the Austrian ten-year average of 10.9 %. Compared to 2022, health expenditure increased nominally (at current prices) by 4.9 % and the GDP by 5.6 % (7, 8).

Healthcare financing in billion euro	2023
Sum of healthcare expenditures	55.2
Ongoing health expenditures	52.8
Ongoing public health expenditures	40.5
Ongoing private health expenditures	12.3

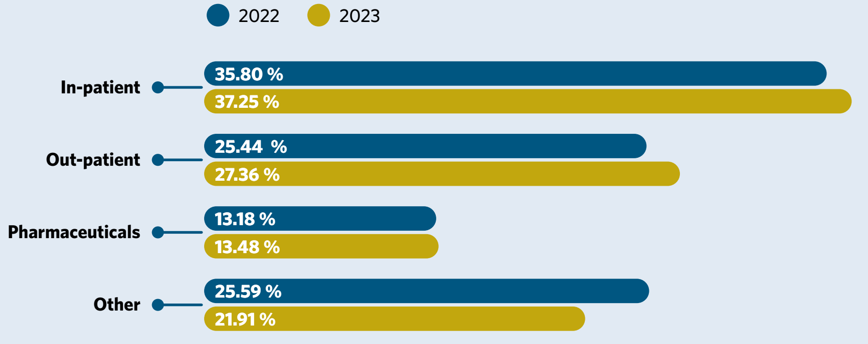
Source: STATISTIK AUSTRIA, Ausgaben für Gesundheit 2023 (7)

Broken down by public and private, more than three quarters of health expenditure is covered by public funds. In 2023, pandemic-related health expenditure went down significantly. However, rising salaries, energy- and operating costs and honorariums still lead to an increase in total expenditure (8).

With the share of current health expenditure of the GDP making up 11.2 percent, Austria ranks sixth among 38 OECD countries (8):

- OECD-Average: 9.2 % of the GDP
- Average of the 22 EU Member states in the OECD: 8,9 % of the GDP
- Countries with the highest health spending compared to economic output: USA (16.7 %), Switzerland (12.0 %) and Germany (11.8 %)

Healthcare spending by type



Source: Berechnet durch das Institut für Pharmaökonomische Forschung (IPF) unter Verwendung folgender Sourcen: IQVIA, STATISTIK AUSTRIA (9)

The largest share (37.25 %) was spent on the in-patient sector in 2023, while 27.36 % was spent on the out-patient sector and 13.48 % 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 2022, spending on in- and out-patient care increased in 2023, while spending for pharmaceuticals remained steady and costs for other areas sunk (9).

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

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 2023 – in % of GDP[1]

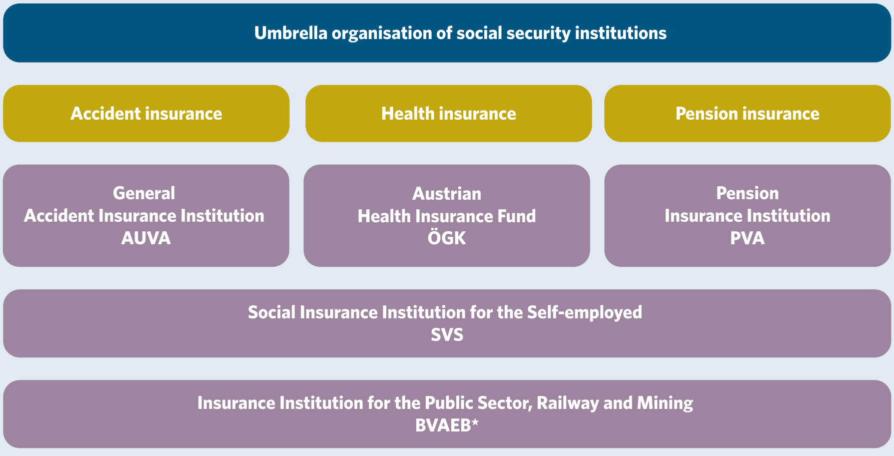
Timeframe	2013	2023
Germany	11.0	11.8*
France	11.4	11.6*
Austria	10.3	11.0*
Belgium	10.6	10.9**
Sweden	10.9	10.9*
Netherlands	10.6	10.1**
Finland	9.8	10.1**
Portugal	9.4	10.0*
Spain	9.1	9.6**
Italy	8.8	8.4*

Source: OECD Health expenditure and financing (10)

[1] selected OECD countries *provisional value **estimated value

1.4 Social Security Structure

Structure of Austrian social security



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

Source: Österreichische Sozialversicherung (11)

The current structure of social insurance, consisting of five insurance institutions and the superordinate umbrella organisation, was introduced on 1 January 2020 (11).

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 (82 % of the Austrian resident population), the Austrian Health Insurance Fund (ÖGK) is the largest statutory health insurance fund in Austria (12).

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

1.5 Financial Management of Health Insurance Institutions

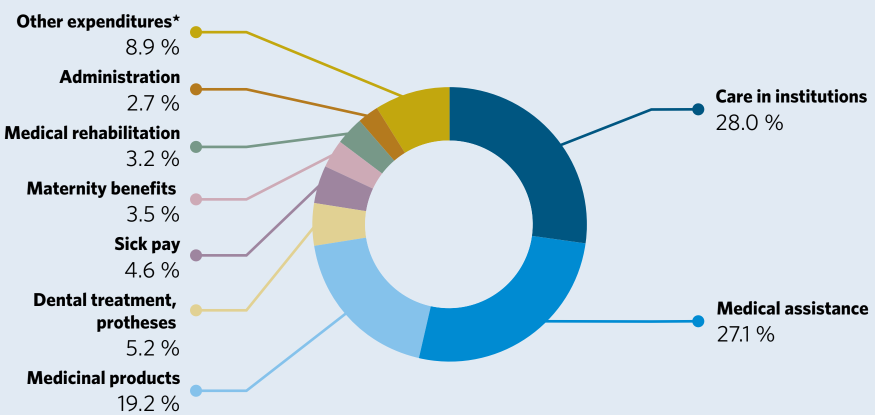
In 2024, the revenue of the statutory health insurance institutions amounted to about 26.8 billion euros, while expenditure amounted to 27.4 billion euros. Compared to 2023, this corresponds to an increase of 9.8 % and 9.6 %, respectively. The result amounted to negative 649 million euros (preliminary financial report 2024). In the 2024 annual average, there were 9.063.328 people eligible for benefits, 79 % of whom were contributors and 21 % were dependants (13).

In 2023 (preliminarily available data), health insurance institutions covered the costs of 111 million packages of pharmaceuticals and spent 4.3 billion (excluding VAT) on them. Each insured person accounted for an average of twelve packages and expenses of 481 euros (14).

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.

These repayments significantly reduce the expenses of the SV and lead to a further reduction in its net expenses. The sum of rebates increases every year.

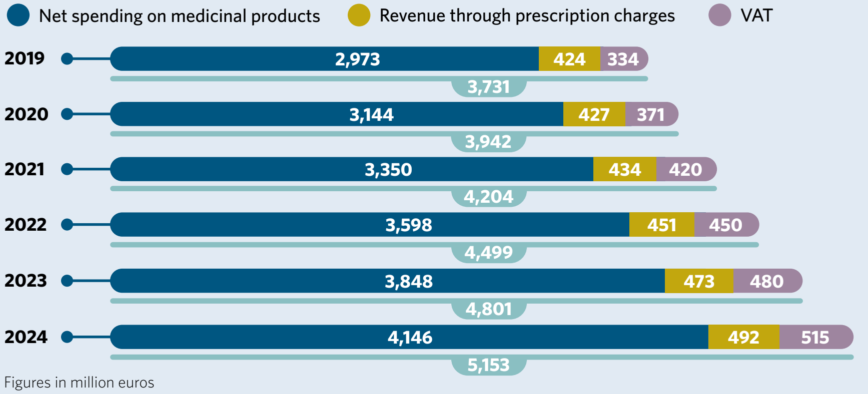
Spending of the health insurance institutions in 2023



Figures as a percentage of total revenue
*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 2025 (vorläufige Gebarung 2024) (13)

Spending on medicinal products

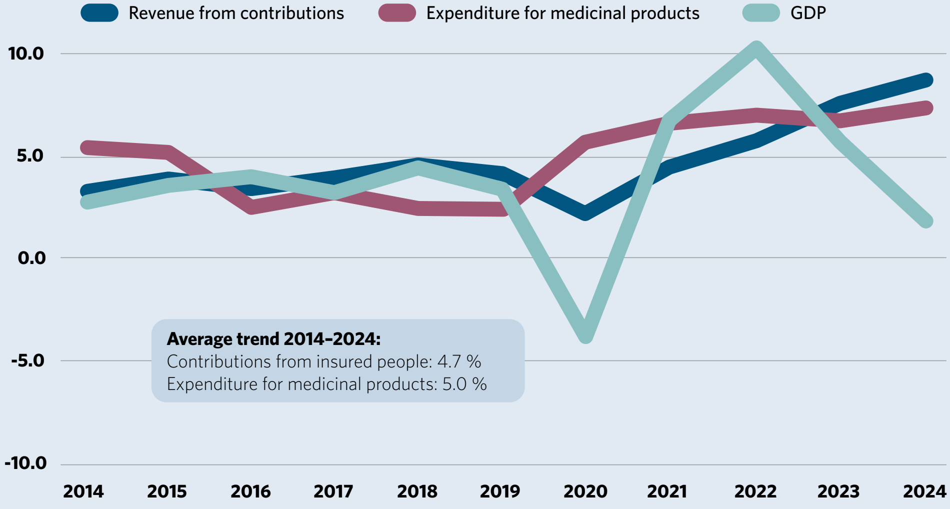


Figures in million euros

Source: Die österreichische Sozialversicherung in Zahlen 2024 und 2025 (vorläufige Gebarung 2024) (13, 15)

The income of health insurance institutions from the contributions of all insured people increased by an average of 4.7 % per year from 2014 to 2024. Over the same period, expenditure on medicinal products increased by 5.0 % (excludes prescription fees collected and individual discounts and repayments from pharmaceutical companies) (15). During the period shown, GDP grew by an average of around 3.8 % annually (16).

Change of revenue and cost for medicinal products 2014–2024



Figures in %

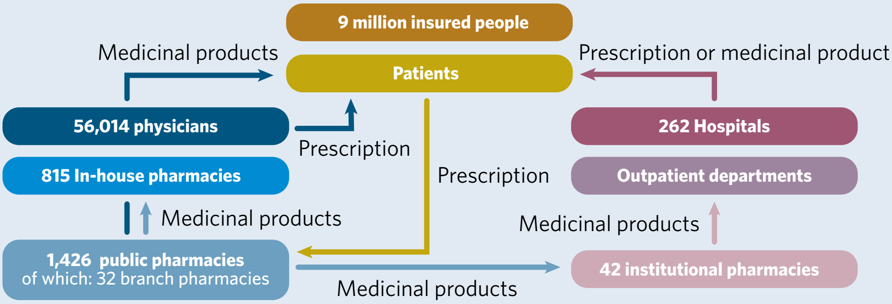
Source: STATISTIK AUSTRIA, Die österreichische Sozialversicherung in Zahlen 2025 (13), Volkswirtschaftliche Gesamtrechnungen (16)

1.6 Structure and Financing of Healthcare

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

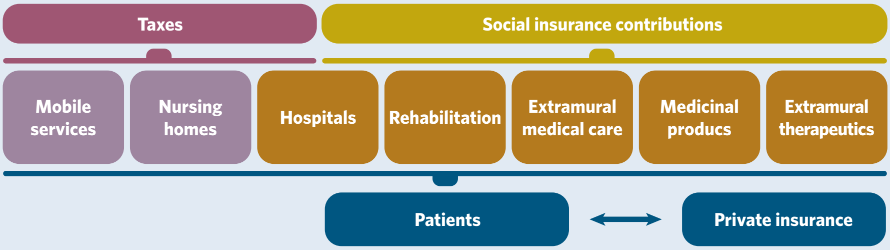
- **Physicians** (general practitioners, group practices, and specialists) **with or without in-house pharmacies**
- **Primary health care units** (PHCU) (currently 97 PHCU, of which 13 paediatric PHCUs) (17)
- **Hospitals and hospital out-patient clinics**
- **Public pharmacies**
- **Other medial/therapeutic services**

Structure of Austria's Healthcare System 2023



Source: Die österreichische Sozialversicherung in Zahlen 2024 (15); STATISTIK AUSTRIA, Einrichtungen und Personal im Gesundheitswesen (18)

Healthcare financing



Source: Das Österreichische Gesundheitssystem Zahlen – Daten – Fakten (19)

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. When a financial equalisation agreement is concluded, 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 outpatient sector, digitalisation, and eHealth, as well as health promotion and vaccination (20).

Health Target Control

The partnership-based target management system for the implementation of the healthcare reform, which has been underway since 2013, pursues the goal of counteracting the strong fragmentation of the healthcare system through joint and cross-sectoral control of the structure, 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 (21, 22).

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 (23).

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

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

With regard to the question of what influence the work of the evaluation board will have on the level of treatment and patients' access to innovative therapies, reference should be made to the level of treatment 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 (24). 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 (25).

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 light of the above, in that the commissions act without instructions in accordance with § 19a (7) KAKuG (26). 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 (27).

It therefore remains to be seen how the work of the evaluation board, which has started its work in 2024, will ultimately affect the supply situation in Austria, in particular on patient’s access to pharmaceutical innovations. In any case, the government program 2025-2029 provides for appropriate “scientific and transparent monitoring of the implementation of the assessment 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 (28).

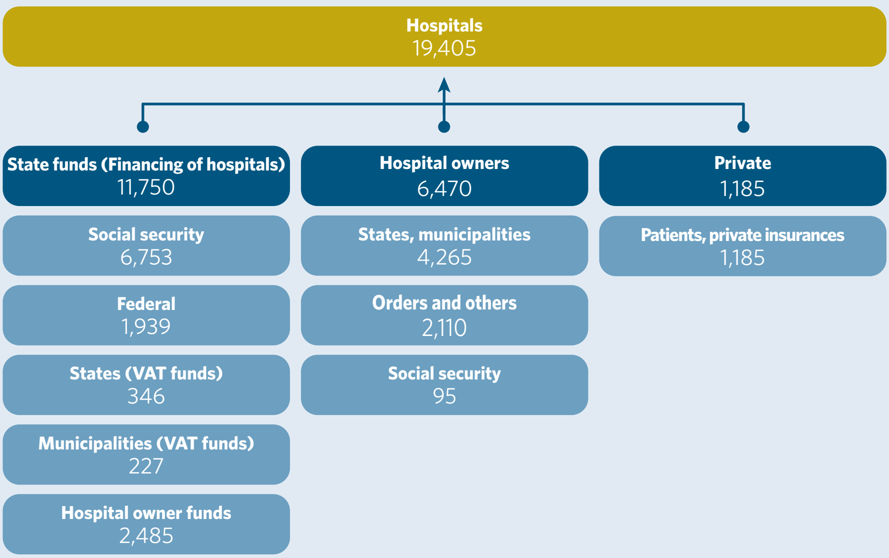
In this context, agreements are concluded between the umbrella organisation of social insurance institutions and the respective hospital operator, which provide for cost sharing for such pharmaceuticals in a specific ratio (29).

This novel instrument is intended, on the one hand, as a more targeted financing of medicines in this interface area. On the other hand, it threatens to complicate and slow down patients' access to therapy, namely because it introduces an additional bureaucratic process, which in turn is linked to potentially lengthy voting procedures (28).

1.7 Financing of Healthcare Institutions

The expenditure of Austrian hospitals that bill according to the LKF scheme (performance-oriented hospital financing) amounted to 19.4 billion euros in 2023. 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 2023



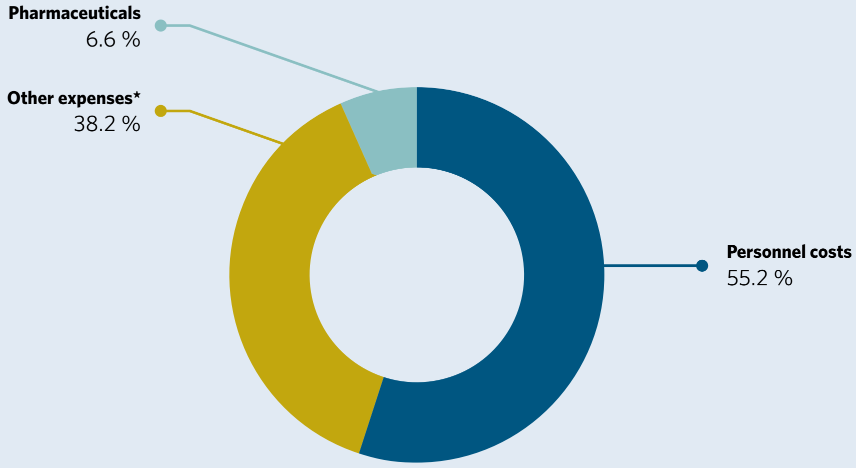
Figures in million euros

Source: berechnet durch das Institut für Pharmaökonomische Forschung unter Verwendung der Daten: Bundesrechnungsabschluss 2023, Krankenanstalten in Zahlen 2023, Statistik Austria SHA (32)

State-funded Hospitals

The total cost of hospitals, that are financed by state health funds (108 hospitals with 39.921 beds (31)), amounts to 19.4 billion euros in 2023. Social insurance paid for a significant portion of the total cost. Of 11.75 billion euros, which were contributed by the state funds, around 60 % was paid by social insurance (32). These costs relate to in-patient and out-patient care. More than 50 % of these costs are attributable to personnel costs, while approximately 6 % are attributable to pharmaceuticals and 38 % to other expenses (30).

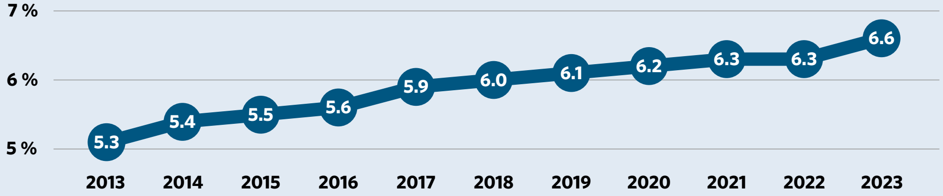
Expenditure in hospitals 2023



*Catering, training, etc

Source: BMASGPK – Kosten der landesfondsfinanzierten Krankenanstalten (30)

Share of medication costs in total costs 2013–2023



Figures in %

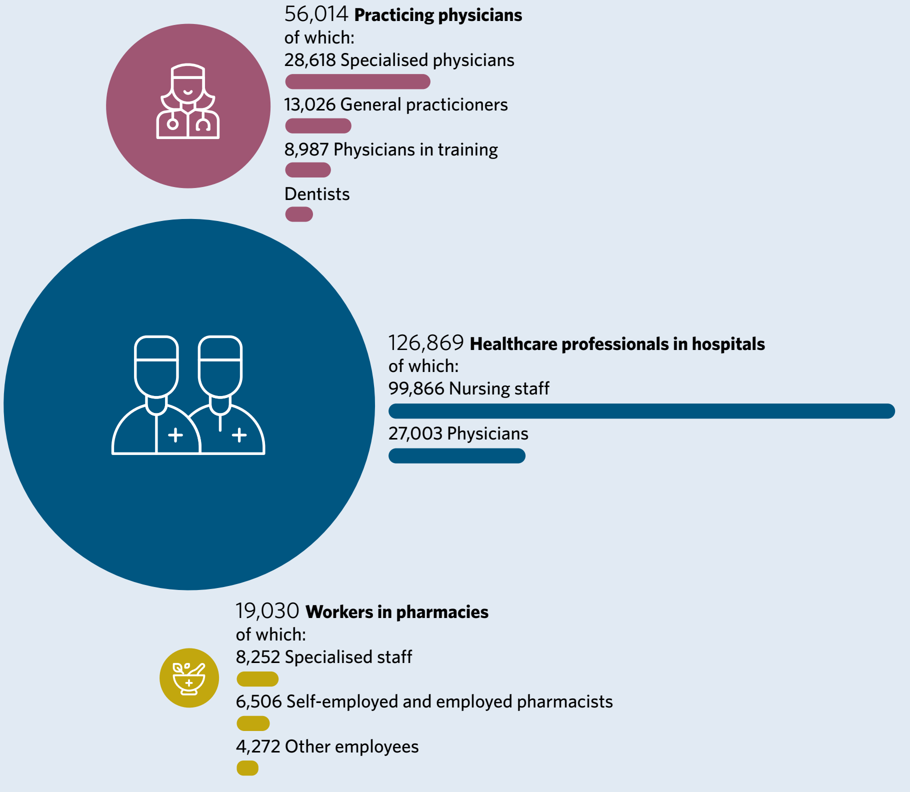
Source: Kosten der landesfondsfinanzierten Krankenanstalten (30)

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 2024, there were 1,426 public pharmacies (with 32 branch pharmacies), 42 hospital pharmacies and 815 self-dispensing doctors in Austria. These provided 9.1 million people with medicinal products (33, 34).

Healthcare workers 2023



Source: STATISTIK AUSTRIA, Einrichtungen und Personal im Gesundheitswesen (18); Österreichische Apothekerkammer (30)

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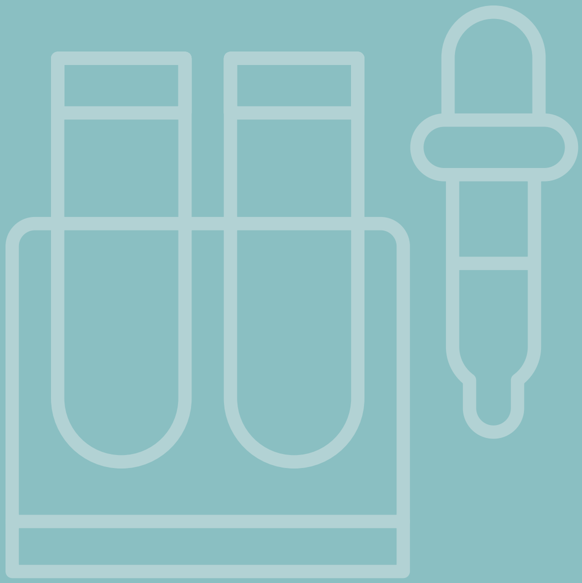
250 clinical trials

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

Research quota in 2024

3.26 %



2. Pharmaceutical Research, Development and Manufacturing

2.1 Austria as a Research Location

In the comparative assessment of research and innovation performance of the EU member states for the years 2017-2024, Austria ranks 6th. The "European Innovation Scoreboard", which is published annually by the European Union, has again classified Austria as a "Strong Innovator" in 2024. Compared to 2017, Austria has shown a significant improvement of 4.6 % with a performance of 116.3 % compared to the EU average in 2024. This puts Austria, together with Belgium, Ireland, Luxembourg and other strong innovators (such as Germany, Cyprus, Estland and France) above the EU average in terms of innovation performance. Denmark, Sweden, Finland and the Netherlands are classified as innovation leaders, with performances well above the EU average (35).

The share of expenditures for research and development (R&D) in the nominal Gross Domestic Product (GDP) is expressed as the **research ratio**, in percent. For 2024, Statistik Austria currently estimates this at 3.35 % for Austria (36). This places the country among the top 3 in the EU, exceeding the European target value of 3 % for the eleventh consecutive time (37).

For 2023, the estimated research quota was 3.23 %. In a comparison of EU countries from 2023, Austria has the third-highest research quota, after Sweden (3.57 %) and Belgium (3.23 %) (36).

According to an estimate by Statistik Austria, 16.6 billion euros were spent on research and development (R&D) in 2024 in Austria (38):

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

Through research contracts, the pharmaceutical industry contributes notably to value creation in Austria: in 2021, Austrian pharmaceutical companies invested 426 million euros in research and development (most recent available figures) (39).

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** on clinical trials on medicinal products for human use 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/EG and had not been completed before 31 January 2025, to the requirements according to regulation 536/2014.

Additional national requirements are regulated in the Austrian Medicines Act in §2a and from §28 to §48. An overview of these legal requirements and recommendations is summarised on the BASG website and the platform of the CTR Ethics Committees (40, 41).

Preclinical Studies

Before an active ingredient can be tested on humans, its safety must be tested in cell models (in vitro tests) and animal models (in vivo tests).

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

Clinical Trials

With the help of many volunteers, new medicinal products can be continuously developed to reduce the suffering of patients and give new hope in 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 (42). 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 ingredient 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 ingredient also has toxic properties (such as some substances used in the field of oncological diseases), only patients with the corresponding disease are included in Phase I-testing.

To minimise the risks for study participants, especially in phase I studies, the European Medicines Agency has published separate guidelines (43). 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.

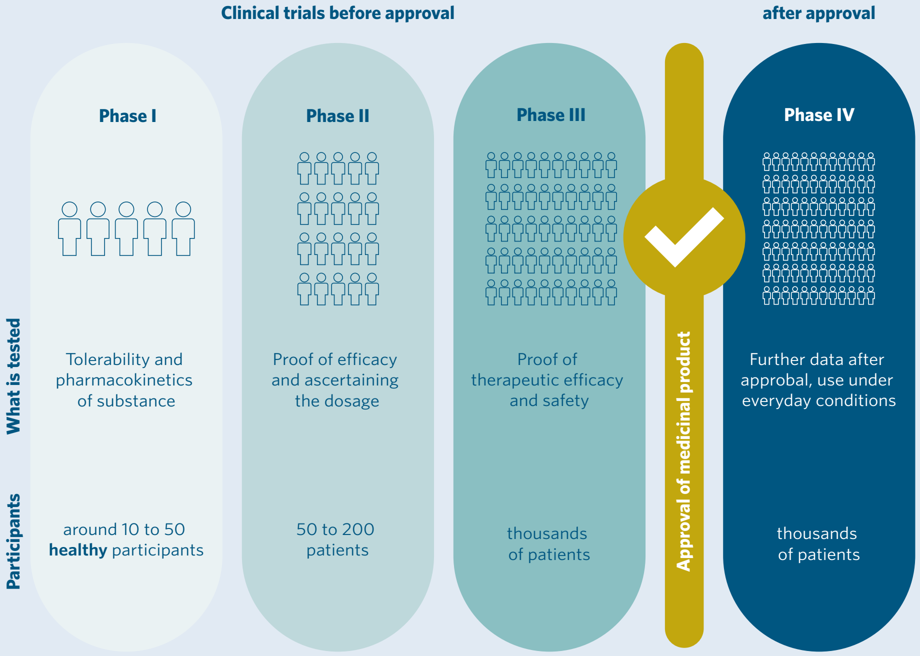
Objective: Documentation of a biological signal to demonstrate efficacy and to determine the best possible therapeutic dosage. Furthermore, information on tolerability and possible interactions is collected. The number of patients with a relevant disease to be examined in this phase is between 50 and 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 ingredient or the control substance is being administered). This is to avoid a possible influence on the treatment result.

Phase III: Proof of Therapeutic Efficacy

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

The duration of treatment for individual patients in the clinical trial depends on the disease, and in the case of chronically progressive diseases, can also be several years. As a rule, these 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 exams, like those of Phase II, are controlled and conducted in a double-blind manner. If phase III of the clinical trial is successfully completed, an application for approval of the active ingredient can be submitted to the appropriate authorities.

The Four Phases of Clinical Trials



Source: adaptiert nach BASG Klinische Studien (42)

Phase IV: Post-Approval Clinical Trials

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

Non-Interventional Studies (NIS)

With the taking effect of the EU Regulation on Clinical Trials with Medicinal Products for Human Use (Regulation (EU) No. 536/2014) on 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 proprietary medicinal product under practical conditions and for documenting side effects that were not recorded in the clinical trial program due to the limited number of cases. The boundary to clinical trials must not be crossed.

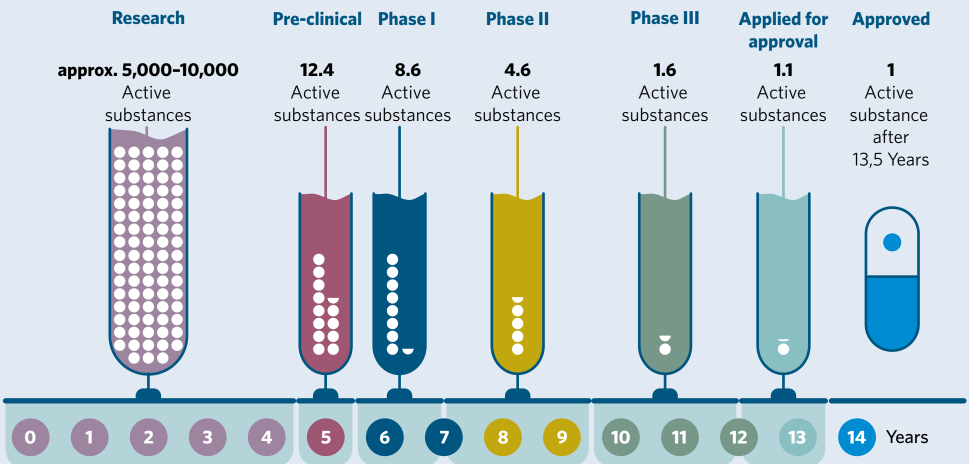
The decision to prescribe the medicine must not be taken at the same time as the decision to include the study participants in the non-intervention study. Furthermore, no diagnostic or monitoring procedures may be used that go beyond normal clinical practice. This is to ensure that the treatment corresponds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

In this regard, the federal ministry of labour, social issues, health, nursing, and consumer protection (BMASGPK) and the federal ministry for safety in healthcare (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 study (44)
- PHARMIG Guideline on Quality and Transparency of Non-Interventional Studies (45)

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) (51)

The development of pharmaceuticals is a high-risk process: On average, only one of 5,000 to 10,000 substances is approved. According to studies, the average cost of developing a new, innovative drug is up to 2.6 billion US dollars (47). These costs include the direct costs of developing the drug, the associated failures and the opportunity costs, i.e. the indirect costs of financing these lengthy and cost-intensive development projects. These high costs arise due to the high documentation and safety requirements for clinical trials and the large number of trial participants required. For many substances, it is only in the extremely costly multinational phase III trials that it becomes apparent that they are not sufficiently effective or have side effects that are too burdensome. The costs of the many failed development projects must also be factored in and borne by the companies (52).

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).

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 2024. 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.

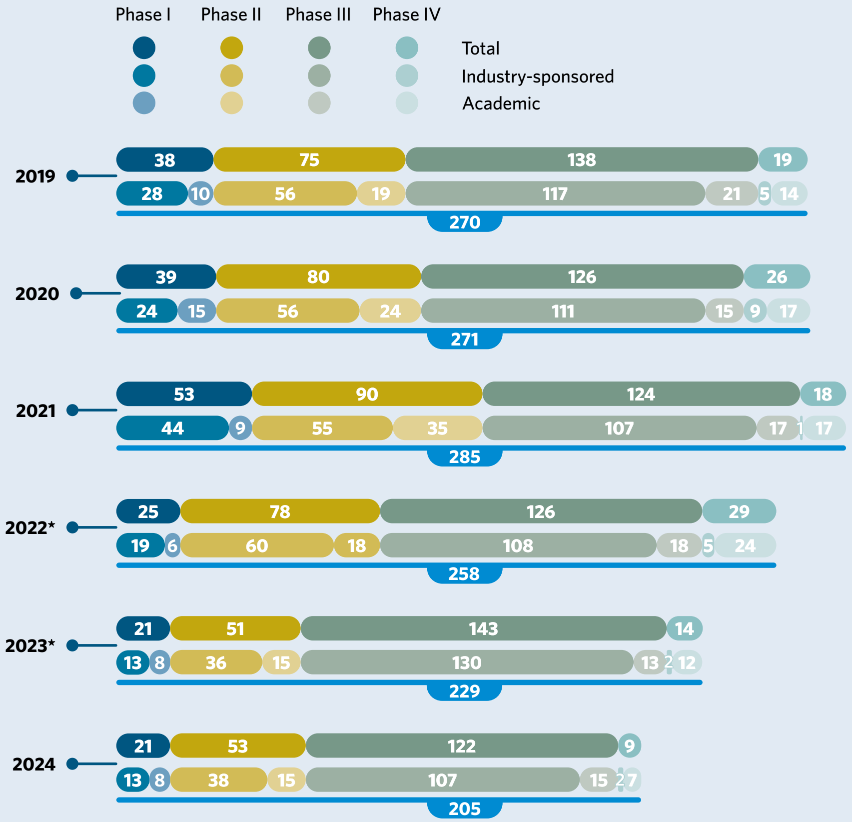
Targeted location initiatives at the beginning of 2024 – such as accelerated procedures or harmonisation for combination studies, medicinal products and medical devices – are important steps that have been introduced to reposition Austria specifically for early study phases.

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. 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.

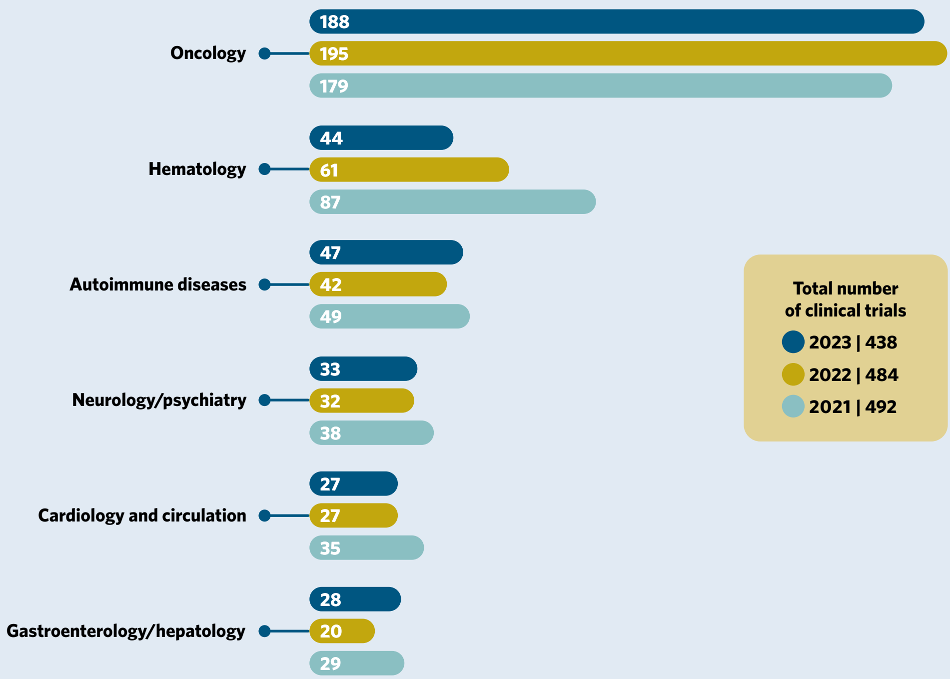
Source: BASG Klinische Prüfungen von Arzneimitteln (40)

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 2021 to 2023, around 32 companies took part in the survey. This corresponds to a market coverage of approx. 78 % (measured by the revenues of all PHARMIG member companies) (48).

Number of clinical trials 2021–2023 broken down by the most researched indications

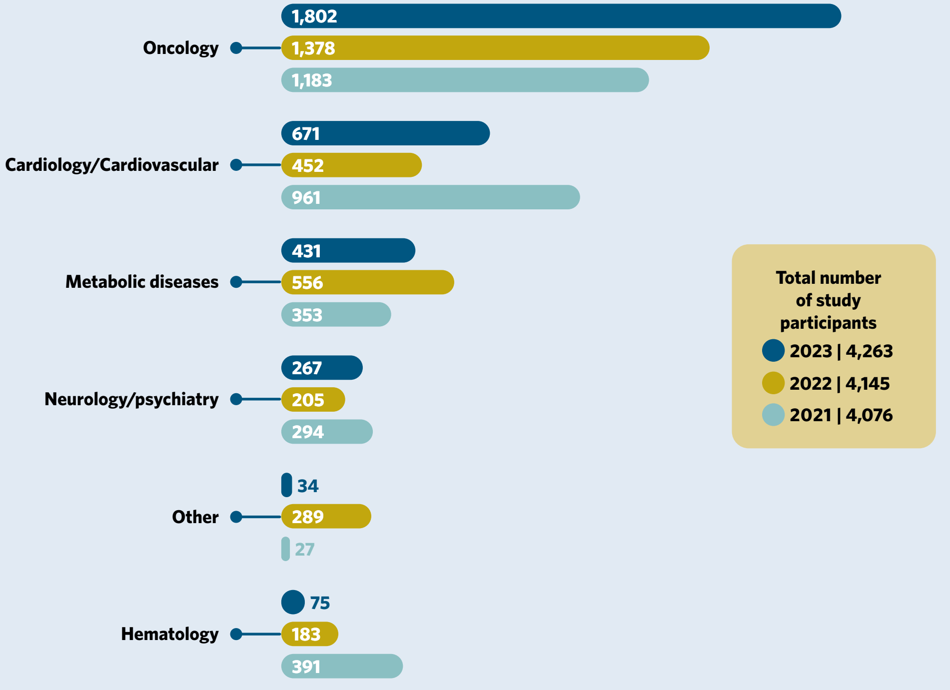


Absolute figures

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2021-2023) (48)

The **average sum** of approx. **471 clinical trials** per year in the years 2021–2023 includes ongoing, started and completed clinical trials.

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



Absolute figures

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2021-2023) (48)

On average, around 4,161 study participants have taken part in clinical trials in Austria between 2021 and 2023. Information on the number of trial participants is provided for an average of 79 % of all clinical trials.

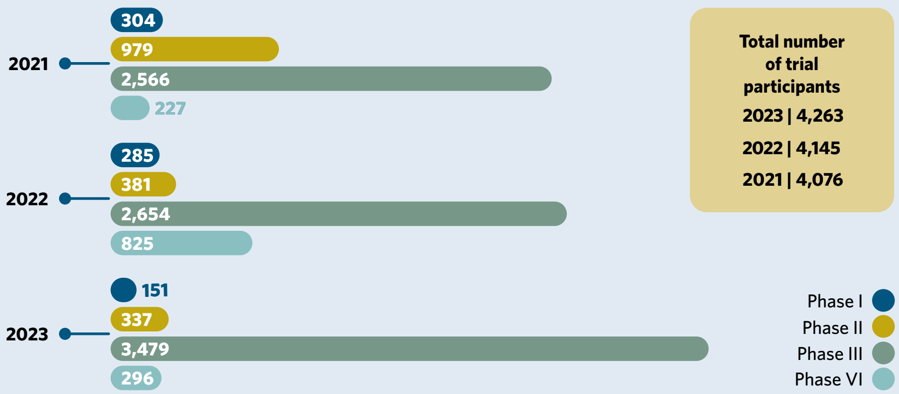
Number of ongoing clinical trials by phase in Austria 2021–2023

Absolute figures

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2021-2023) (48)

Additionally, the support of the pharmaceutical industry enabled an average of 111 "Investigator Initiated Trials", meaning academically funded research projects, per year in 2021–2023.

Distribution of study participants in ongoing clinical trials by phase in Austria 2021–2023

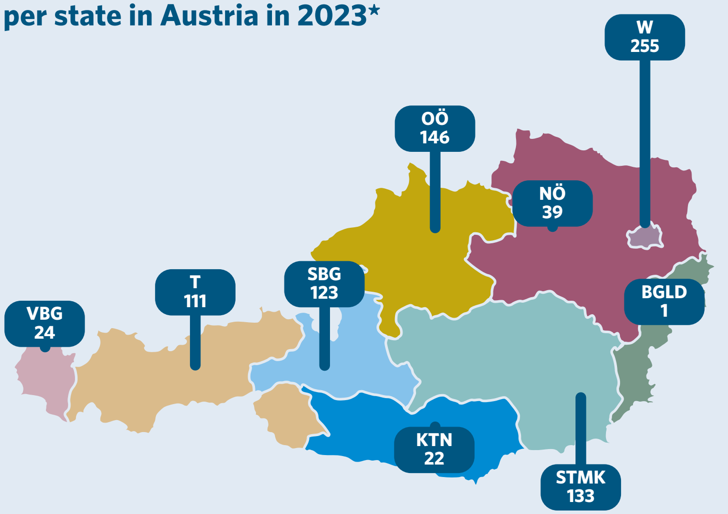


Absolute figures

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2021-2023) (48)

Information on the number of study participants was provided for an average of 79 % of clinical trials.

Distribution of ongoing clinical trials per state in Austria in 2023*



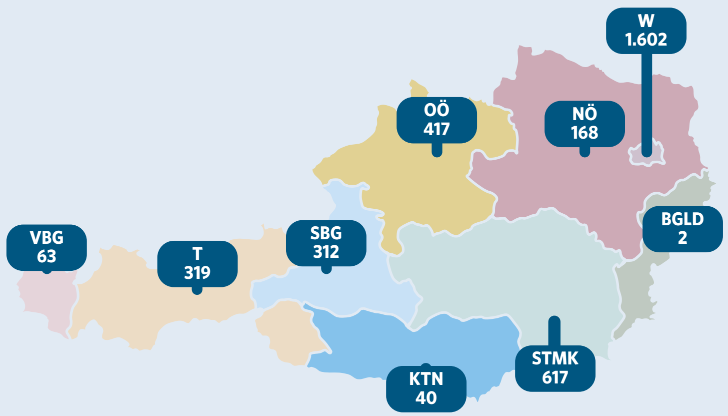
*Data on 76% of the clinical trials. | Absolute figures
Most ongoing clinical trials in Austria are multinational and multicenter, i.e. a clinical trial can run in two or more federal states or centers

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2021-2023) (48)

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

Source: Einwohnerzahl: STATISTIK AUSTRIA, Stand 01.01.2023

Average number of study participants in ongoing clinical trials per state in Austria in 2023*



*Information on the number of patients and federals state distribution for 76 % of clinical trials. | Absolute figures

Source: PHARMIG – Umfrage zu Industrie-gesponserter klinischer Forschung in Österreich (2021-2023) (48)

Paediatric Pharmaceutical Research

50–90 % of the medicinal products commonly used in paediatrics are not approved for children because children and adolescents have long been excluded from clinical research due to ethnic concerns and legal frameworks. However, an adequate supply of medicinal products that have been tested and approved specifically for children is necessary and has therefore been required by EU regulations since 2007 (49).

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 (50).

Transparency of Study Data

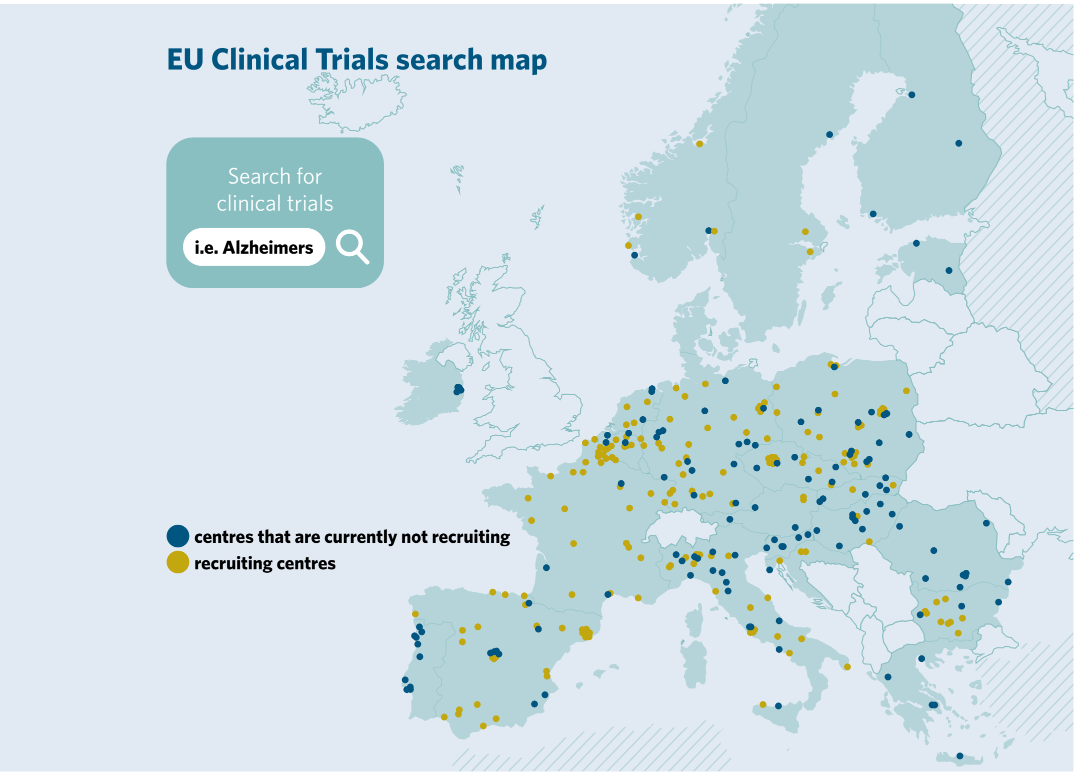
Worldwide register:

- The U.S. National Institute of Health (NIH) has maintained the largest public registry **ClinicalTrials.gov** since 2000. It publishes clinical trial data from all 50 U.S. states and another 200 countries (51).

Register 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 (52).
- Data on clinical trials conducted in the EU, Iceland, Liechtenstein and Norway since 31 January 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) (53). The essential information on these clinical trials can also be accessed via a map search function that is easy to understand for laypersons (54).

EU Clinical Trials search map



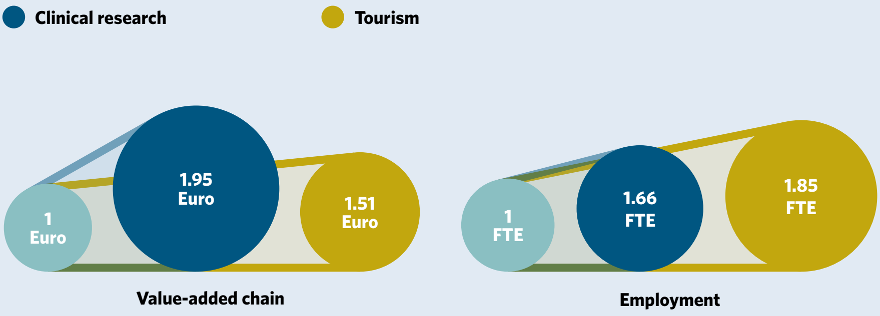
Source: eigene Gestaltung nach EMA Clinical Trials Search (54)

- 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 (55). 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)) (56).

The Value Creation of Industry-Sponsored Clinical Trials

The added value generated from the conduct of industry-sponsored clinical trials in Austria amounts to 144.2 million euros per year. Each year, a medical treatment value of 100 million euros was funded through 463 industry-sponsored clinical trials with an average value of medical treatment of 37,068 euros per recruited person. The value of this treatment includes the free investigational medication, the assumption of the costs for diagnostics, and therapy as well as administrative services and documentation. This represents a significant share of 0.3 % of current annual health expenditure (57).

Industry-sponsored clinical trials



Source: Walter E., Economic impact of industry-sponsored clinical trials of pharmaceutical products in Austria (57)

Every euro invested by the pharmaceutical industry in clinical trials generates 1.95 euros for the Austrian economy. Jobs in the order of 2,021 full-time equivalents (FTE) are created and secured, resulting in an employment multiplier of 1.66 (57).

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

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

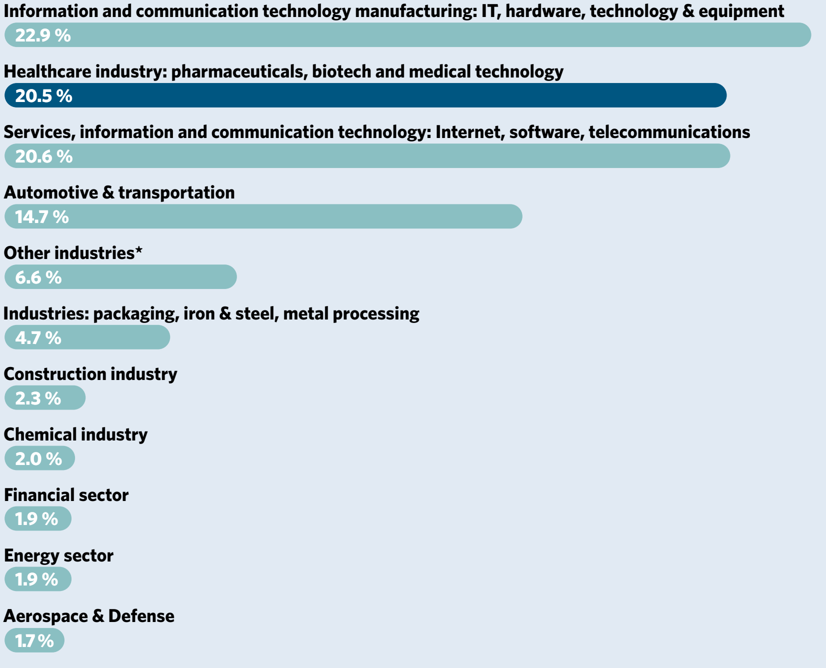
Source: Walter E., Economic impact of industry-sponsored clinical trials of pharmaceutical products in Austria (57)

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

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)



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

Source: 2024 EU Industrial R&D Investment Scoreboard (58)

In research and development, the "healthcare industry" (pharmaceutical, biotech, and medical technology industry) ranks second behind the information and communication technology sector: 258.1 billion euros were invested in research and development in 2023, which corresponds to approx. 21.9 % of revenue (58).

2.4 Special Challenge – Antibiotics Development

Antimicrobial resistance (AMR) causes 35,000 deaths per year in the European Economic Area alone, with costs to the healthcare system and productivity losses estimated at 1.5 billion euros per year. According to the United Nations Environment Programme (UNEP), without coordinated measures, ten million people worldwide will die from AMR every year (59).

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 (60, 61).

- Between 2017 and 2023, only ten new antibiotics and combinations were approved, 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 (62).

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.

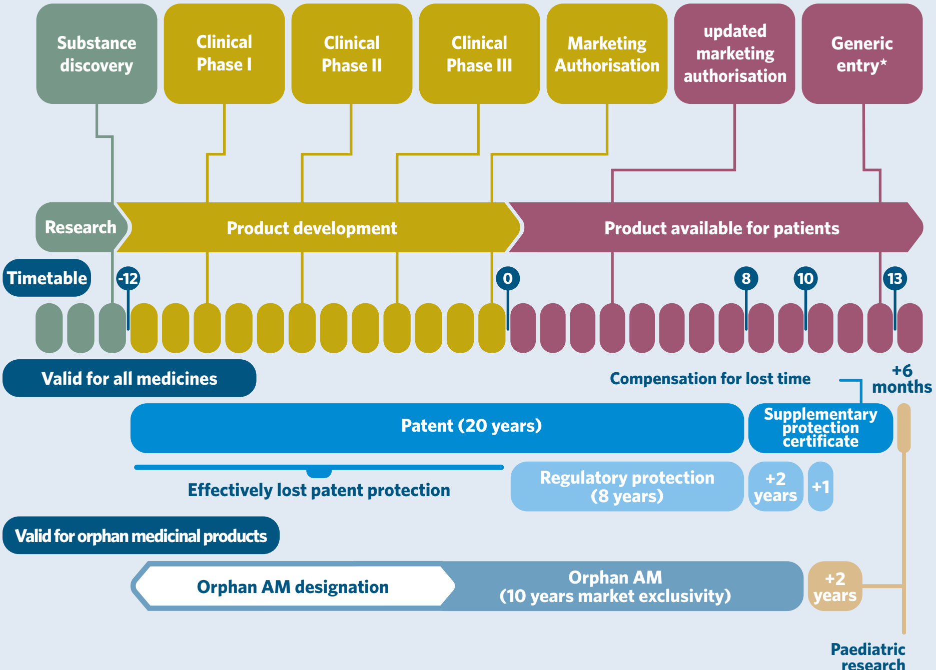
The protection of intellectual property is the best incentive for investment in research and development.

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 approval as a proprietary 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 (61).

In 2023, the pharmaceutical industry filed 12,425 patent applications with the World Intellectual Property Organisation (WIPO) (63).

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 ingredient (generics) or with similar active ingredients (biosimilars) (see Section 3.2). As a result, the original preparation can usually no longer contribute to the refinancing of research and development costs after the expiry of the corresponding IP rights.



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

Source: IQVIA, PHARMIG

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 ingredients, 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 approval (MA)
- Only for products with an authorisation
- Only one SPC per product (i.e. either active ingredient 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 if 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 approval 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).

9.310

Authorised human medicinal specialties in Austria

110

Authorisations for medicinal products in the EU in 2024

208

new medicinal products in the last five years in Austria, of which 38 in 2023

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 Ingredients

Active ingredients 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 ingredient and the packaging material.

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

Specialty 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 2022 to 2024, the European Medicines Agency (EMA) recommended 280 medicinal products for authorisation, 126 of which contained a new active ingredient. Most innovations in 2024 were in the fields of oncology and haematology (76-78).

	EMA recommendations for authorisation	Of which with new active ingredient
2022	89	41
2023	77	39
2024	114	46
Total	**280**	**126**

Source: EMA. Human medicines: highlights of 2022, 2023, 2024 (76-78)

Innovations 2024 (78):

- 114 new medicinal products for human use were recommended for authorisation by the EMA.
- 46 of these contain new active substances.

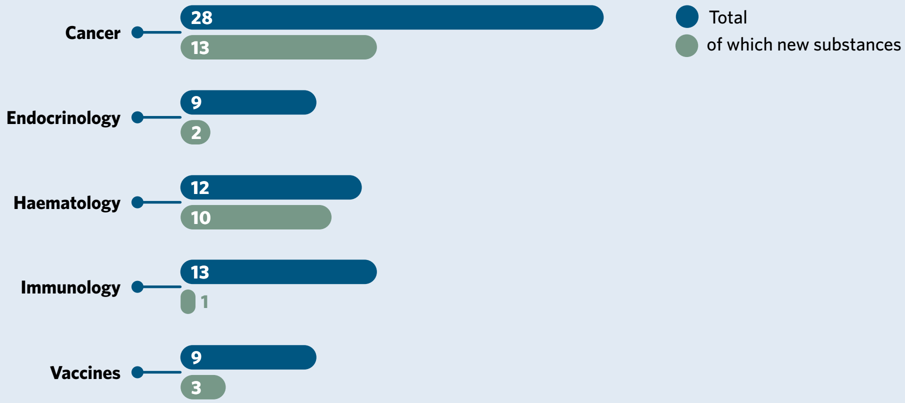
- 25 veterinary medicinal products were recommended for authorisation by the EMA.
- 2 of these contain new active substances.

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:

- The first medicinal product for the treatment of early-stage Alzheimer's disease
- The first needle-free and smaller form of adrenaline to treat allergic reactions
- The first vaccine in the EU to protect against the Chikungunya virus
- The first treatment for tumours associated with Von Hippel-Lindau syndrome
- Two new antibiotics for the treatment of certain serious infections

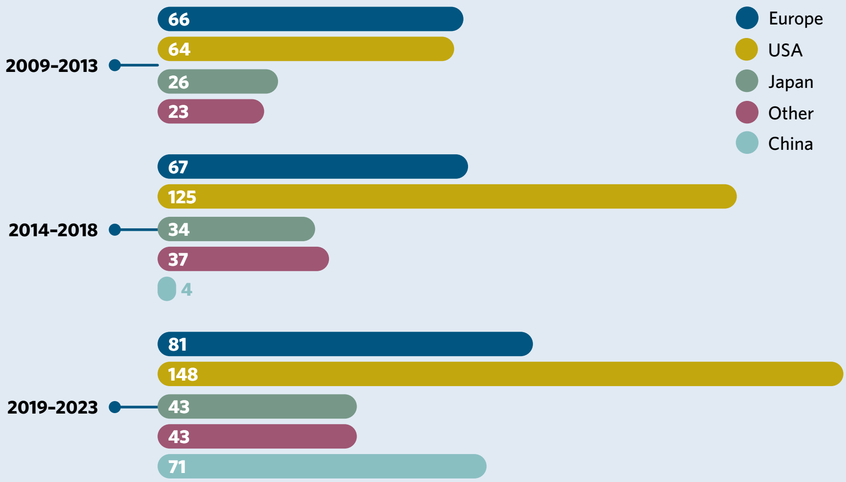
Selected* innovations per area



*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 2024 (78)

New substances by region



Absolute figures

Source: EFPIA - The Pharmaceutical Industry in Figures (79)

In the last five years, a total of **208 medicinal products** with a new active substance have been authorised in Austria. On average, 42 new treatment options are available each year.

Number of Innovations in Austria

2024	2023	2022	2021	2020
38	36	54	41	39

Absolute figures

Source: BASG 2025

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 (80):

- **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 (81) and Regulation (EC) No. 1394/2007 (82) and are subject to Europe-wide authorisation in accordance with Regulation (EC) No. 726/2004 (72).

As of March 2025, 19 ATMPs are authorised in the EU, 15 of which are medicinal products for rare diseases (83):

- 16 gene therapy medicinal products
- 1 (somatic) cell therapy product
- 2 biotechnologically processed tissue products

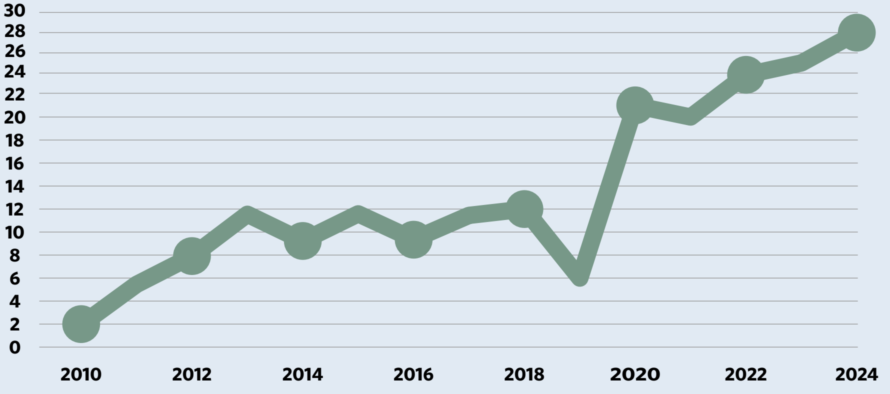
Medicinal Products for the Treatment of Cancer

In Austria, over 44,000 people are diagnosed with cancer every year. The number of new oncological cases will continue to rise in the coming years due to the increasing proportion of older people. Although cancer is still the second most common cause of death in Austria, the chances of survival are increasing. This is primarily due to evidence-based and timely early detection, diagnosis and treatment (84).

Current Overview (78, 85)

- As of April 2025, 351 medicinal products have been authorised for the treatment of cancer in the EU.
- In the last two years alone, 46 new cancer drugs have been authorised in Europe.
- In 2024, the EMA recommended 28 medicinal products for authorisation, 13 of them with a new active substance.

Number of medicinal products for curing cancer recommended for approval



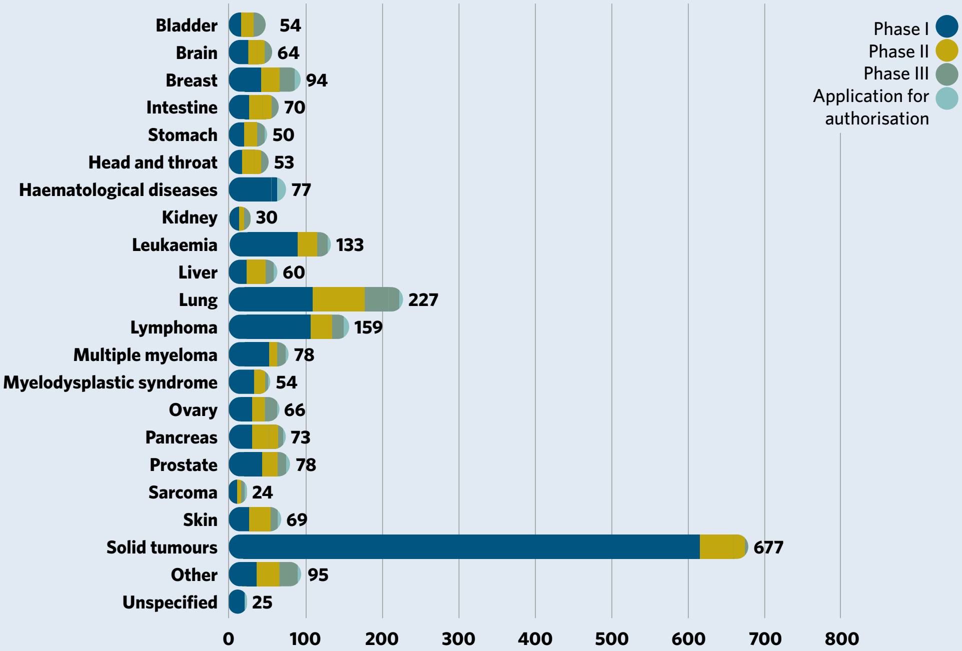
Source: EMA. Human medicines in 2024 (78)

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 (61).

In 2023 alone, more than 2,000 new clinical trials were started in oncology with novel treatment methods, including cell and gene therapies, antibody-drug conjugates, multispecific antibodies and radioligand therapies (86).

Medicinal products and vaccines in development against cancer



Source: PhRMA – Medicines in development for cancer, Report 2023 (87)

Oncology is also the most researched therapeutic area in Austria (approx. 43 % of industry-sponsored clinical trials) (see Section 2.2 Clinical research) (88).

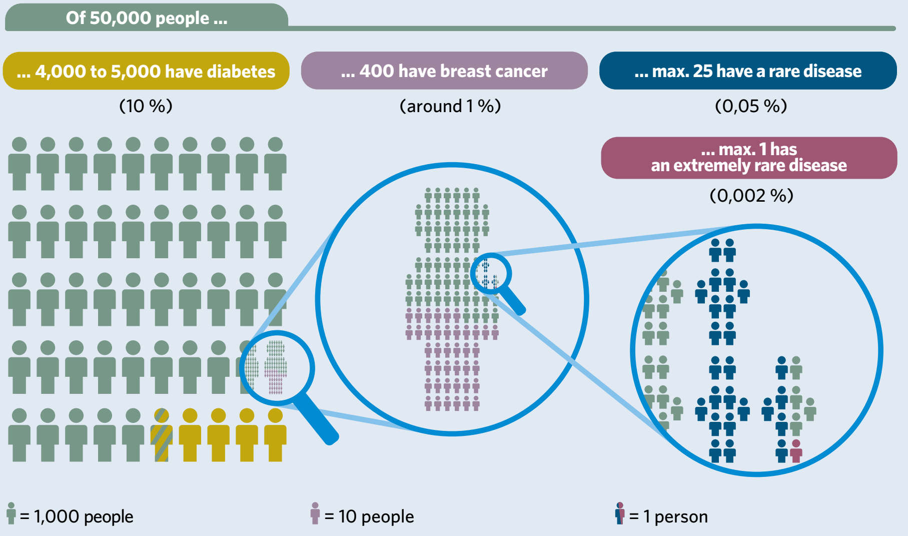
Medicinal Products for the Treatment of Rare Diseases

Rare diseases are life-threatening or chronically debilitating diseases that affect fewer than five in 10,000 people on average in Europe. Of the approximately 30,000 known diseases, more than 6,000 are rare diseases, more than 50 % of which affect children. In Austria, around 450,000 people (corresponding to 5 % of the population) suffer from rare diseases; in the EU, the figure is estimated at 36 million (one in twelve people are affected) (89, 90).

Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products (91) 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 (92).

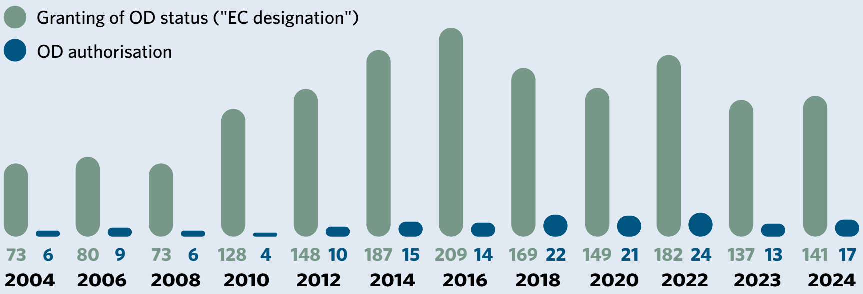
What is rare? A comparison



Source: PHARMIG

In the years 2000–2024, 4,586 applications for orphan drug status were submitted. 3,012 of these were granted, of which only 261 have received orphan drug status to date. The high number of applications reflects the pleasingly high level of research activity in this area and shows that the incentives offered by the regulation are being accepted. However, the low success rate also illustrates the high entrepreneurial risk. In 2024, 17 orphan drugs received marketing authorisation (93).

Orphan drugs 2004 to 2024
Granting of status vs. authorisation



Figures in absolute terms

Source: EMA, Orphan Medicinal Product Designation Overview 2020-2024 (94)

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.

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 (96) as well as the evaluation of the report (2020) (95) 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 (96).

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, 172):

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 production 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 2024, there were 98 vaccine candidates in the pipeline, 93 of which were prophylactic vaccines and five therapeutic vaccines (against infectious agents) (101).

The most common vaccine candidates:

- COVID-19/SARS-CoV-2: 15 (also in combination with other coronaviruses)
- Seasonal influenza: 13
- Respiratory syncytial virus (RSV): 7
- Pneumococcal diseases: 5

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

42 % 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, 14 vaccine candidates are directed against antibiotic-resistant bacteria on the WHO's list of priority bacterial pathogens.

Overview of the Vaccine Pipeline in Europe

98 vaccine candidates in development

42 % of these are vaccines **in new vaccination indicators**

10 are for **travellers**

64 % are aimed at **respiratory-transmissible** infections

14 are aimed at **antibiotic-resistant** germs

81 are for **adults**

Source: Vaccines Europe pipeline review 2024 (101)

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 (102).

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 (103).

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 Production and Quality Assurance

Areas of Pharmaceutical Production

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

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

GMP – The Basic Rules of Production

The manufacture of medicinal products must be carried out in accordance with Good Manufacturing Practice (GMP), which prescribes proper, hygienic, well-documented and controlled production (104).

GMP covers the following topics, among others:

- Duty of care
- Staff training
- Premises
- Separation of production, packaging and storage
- Testing
- Labelling
- Hygiene
- Quality of materials
- Rules for self- and third-party inspection
- Supplier qualification
- In-process controls
- Validation
- Quality control
- Deviation management
- Change management (change control)
- Complaints and recalls

National and International Requirements

GMP defines guidelines for the quality assurance of production processes and the environment in the production of medicinal products and active pharmaceutical ingredients (104). Quality assurance plays a central role in pharmaceutical manufacturing, as quality deviations can have a direct impact on patient health.

Corresponding guidelines have been drawn up, for example, by the European Commission, the Pharmaceutical Inspection Co-Operation Scheme (PIC/S), the US Food and Drug Administration (FDA) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (105). In Austria, the implementation into national law is mainly carried out by means of the Medicinal Products Act (106).

The health authorities of the respective countries are responsible for monitoring compliance with the applicable regulations. In Austria, this enforcement authority is the BASG and the AGES medical market surveillance organisation that supports it.

Measures Against Counterfeit Medicinal Products

Safety features on each medicinal product pack should make any tampering with the packaging immediately recognisable and ensure traceability of the medicinal product from the manufacturing company to the pharmacy (see chapter 4.2).

3.6 Authorisation Procedures

Medicinal products may only be placed on the market by the marketing authorisation holder if they have been officially approved 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 proprietary medicinal product and a registration of a traditional herbal, homeopathic or proprietary 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 approval is carried out by the BASG (Federal Officefor 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 approval 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 (81).

Central Procedure (EU)

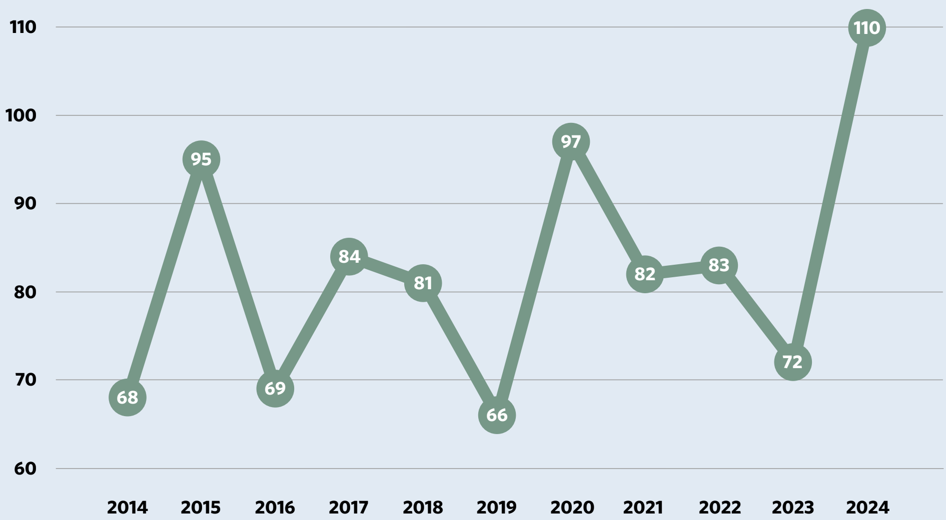
Since 1995, there has been a central authorisation procedure in which a European authorisation is issued at the end. The central authorisation is issued by the EU Commission and is valid in all EU member states. Legal basis: Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 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

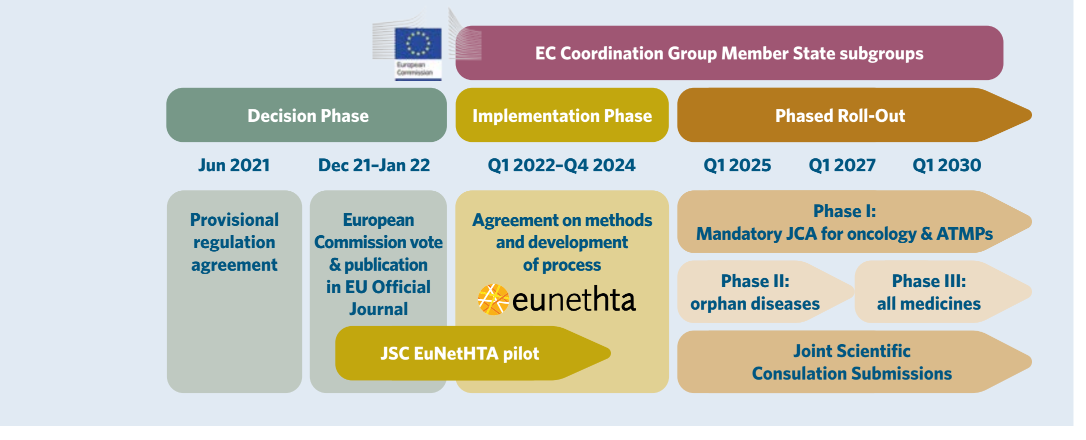


Source: Europäische Kommission

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 (107). 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 (108).



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) (109).

The legal basis is the Health and Food Safety Act (GESG) (110).
(medicinal products for human use incl. homeopathic medicinal products)

Number of authorised human medicinal products 2024*	9,310
Chemical medicinal products	8,178
Homeopathic medicinal products	521
Biological medicinal products	361
Herbal medicinal products	161
Radiopharmaceuticals	48
Medical gases	41

Source: BASG-Statistiken zu Arzneimitteln (111)

*excl. EU authorisations

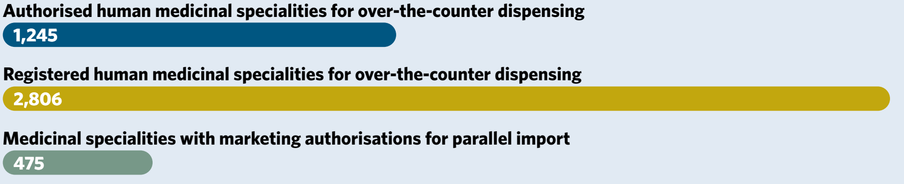
Number of registered human medicinal products 2024	2,968
Homeopathic medicinal products	1,974
Pharmacy's own medicinal products	621
Traditional herbal registrations	211
Allergen manufacturing processes	162

Source: BASG-Statistiken zu Arzneimitteln (111)

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) (112, 113).

Further Figures for 2024



Figures in total | As at 29 January 2025

Source: BASG Statistiken zu Arzneimitteln (111)

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

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

The objectives of pharmacovigilance are:
- The prevention of harm from side effects from the use of medicines within and outside the scope of their regulatory approval, or from occupational exposure.
- Promoting the safe and effective use of medicinal products, 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.

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. 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).

Good Pharmacovigilance Practices (GVP) describe measures in a series of modules that are intended to standardise and facilitate the implementation of pharmacovigilance activities in the European Union (115).

4.1 Post-authorisation Pharmacovigilance

The European Commission and 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 side effects.

Usually, only a limited number of patients take part in clinical trials for a fixed period of time under controlled conditions.

Under real-life conditions, a larger and more heterogeneous group of patients will use the medicinal product. They may suffer from different diseases and also take other medicinal products.

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

The Black Triangle

The European Union has introduced 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 ingredient 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) (116).

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

Adverse Reaction Reporting and Assessment

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

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

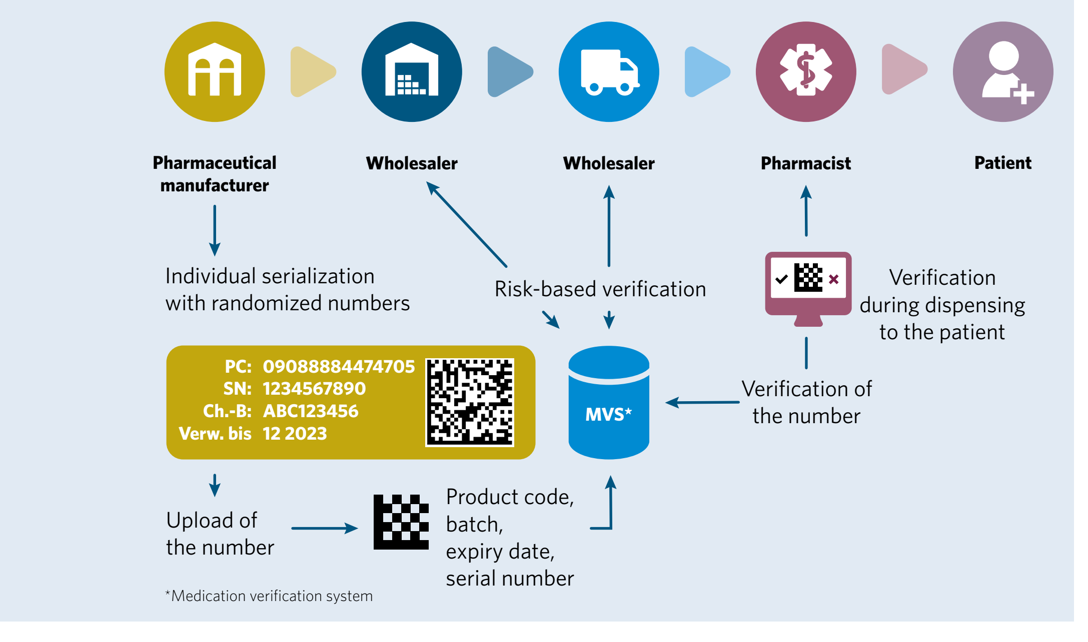
Marketing authorisation holders of medicinal products submit all suspected adverse reactions that have occurred in Austria, as well as side effects from use observations and case reports from the literature, directly to the EMA's EVPM (EudraVigilance post-authorisation module).

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

4.2 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 (117). 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.

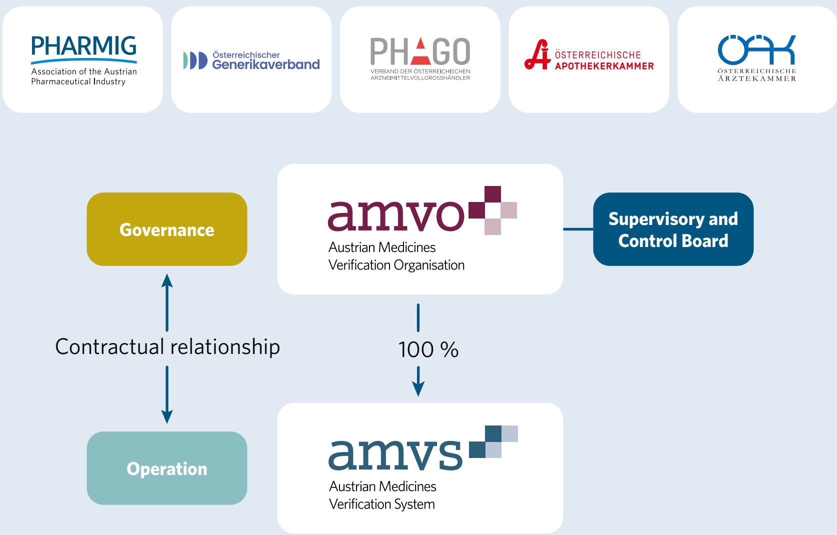
Implementation in Austria

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

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



Source: PHARMIG

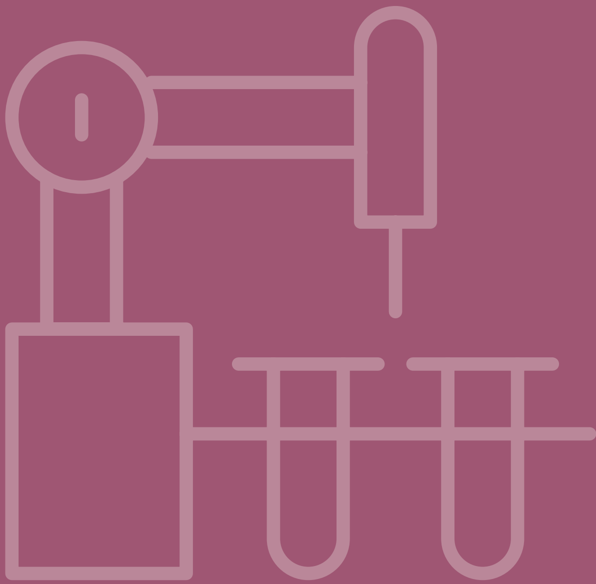
The pharmaceutical industry creates

2.3 million jobs

across Europe and its economic contribution is estimated at 2.0 % of the gross value added of the 27 EU member states.

Export Country

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



5. Pharmaceutical Industry as an Economic Factor

5.1 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 people. 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 (118).

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 (118)

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 (118)

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 (119).

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 (119)

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

Source: PwC. Economic Footprint of the Pharmaceutical industry in Europe (119)

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

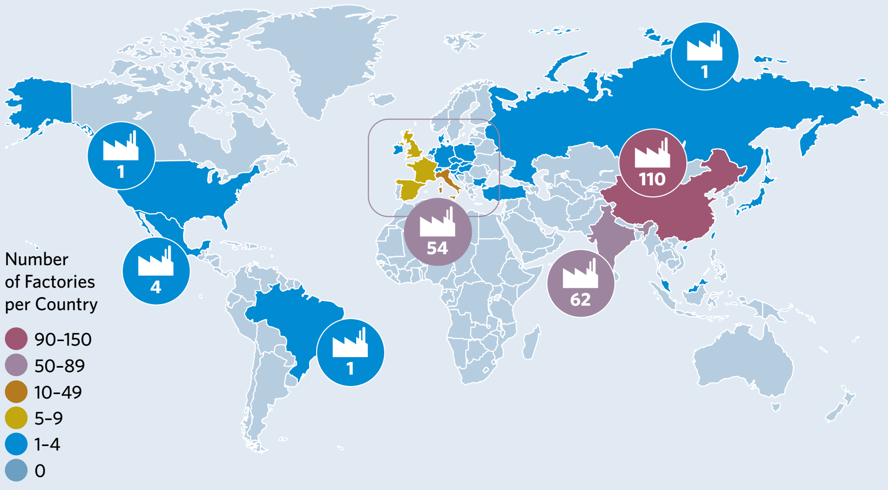
European comparison of pharmaceutical production in 2022

Country	Production in million euros
Belgium	40,959
Germany	37,405
Slovenia	6,955
France	32,773
Ireland	19,305
Italy	49,000
Netherlands	6,180
Denmark	21,501
Austria	**1,453**
Poland	2,903
Portugal	2,334
Sweden	11,910
Switzerland	56,641
Spain	22,957
United Kingdom	29,044

Source: EFPIA The Pharmaceutical Industry in Figures 2024 (79)

In 2022, Switzerland, Italy, Belgium and Germany were responsible for the majority of pharmaceutical production in Europe (79).

However, the example of antibiotic active ingredients shows how much Europe is dependent on Asia for the production of pharmaceuticals. For example, 60 % of active ingredient manufacturers are based in China or India (120).



Source: Pro Generika (120)

5.3 Importance of the Pharmaceutical Industry in Austria

Trade Balance of Pharmaceutical Products 2023

	Import		Export	
Change	+11.8 %		+20.2 %	
Year	2022	2023	2022	2023
Value	12,599	14,088	13,735	16,510

In millions of euros | Status of the information: February 2025

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

Austria is one of the exporting countries in the pharmaceutical industry: in 2023, Austria had a positive trade balance (2,422 million euros), meaning that more goods were exported than imported.

Compared to 2022, when pharmaceuticals worth 1,453 million euros were produced in Austria, production in 2023 more than doubled to 3,284 million euros. The increase can be attributed, among other things, to increased production capacities following the pandemic and increased investment by companies in Austria as a pharmaceutical location.

Austria has established itself as an important location for the pharmaceutical industry – particularly in the areas of plasma production, vaccine development and antibiotic production – with, for example, the only fully integrated penicillin production facility in Europe that covers all steps from the extraction of active ingredients to the finished medicinal product.

5.3.1 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 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 60 authorised medicinal products), 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 around 55 years, making it the longest tradition in Europe.

Contribution of **plasma production** in Austria to local economic performance:
- 24 plasma centres with more than 400 employees (121)
- Donation of 400,000 litres of plasma per year (2023)
- 58 litres of plasma per 1,000 inhabitants
- Contribution of 1.5 to 5 million euros per plasma centre per 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 around four million litres of plasma per year (approx. 15 % of global capacity)
- Creation of more than 5,000 jobs in the plasma processing companies
- Sustainable value creation also through job creation at supplier companies that supply the sites
- Exports 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.

5.3.2 Vaccine Production in Austria

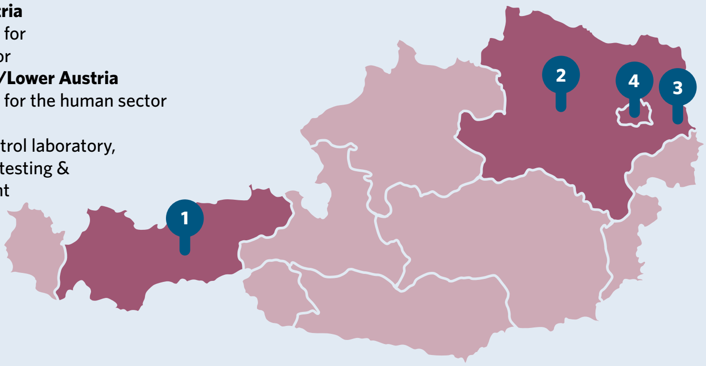
There are only a few pharmaceutical companies in the world that specialise in the complex production of vaccines. Vaccines are highly complex pharmaceutical products that require lengthy production processes (around 12 to 36 months) and a large number of control procedures. Austria plays an important 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 (122).

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) (122)

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 (123).

5.3.3 Antibiotics Production in Europe

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 ingredients and more than 240 million drug 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 ingredient to the finished form, the entire production process takes place at a single location, from the active ingredient to the finished packaged antibiotic tablet. This is unique in Europe (124).

5.4 Austria as a Pharmaceutical Location

The Austrian pharmaceutical companies, which either produce medicinal products themselves ("manufacturers") or import finished medicinal products to Austria ("distributors"), differ greatly in their business volume. In addition to international corporations, the corporate landscape is characterised primarily by small and medium-sized enterprises (SMEs). Turnover ranges from a few 1,000 euros to 250 million euros per year.

18,000

Employees in companies in the Austrian pharmaceutical industry (63,000 indirect employees)

9.6 billion euros

is the pharmaceutical industry's share of value added (=2.8% of GDP)*

3.2 billion euros

Investments by pharmaceutical companies in Austria as a business location (2013-2020)

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

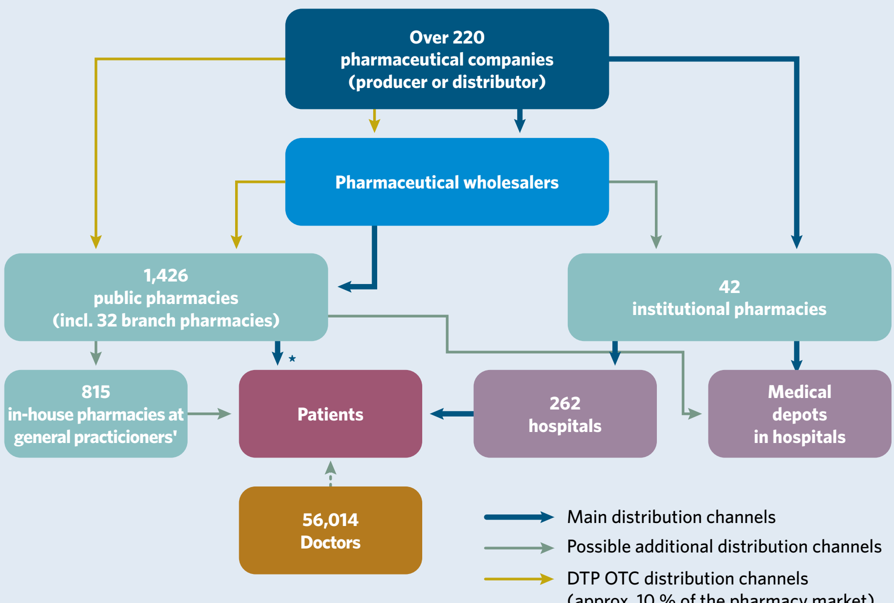
Sourcen: Haber, G. (2016): Life Sciences und Pharma: Ökonomische Impact Analyse; firmeneigene Veröffentlichungen 2013-2020

Each individual company makes a significant contribution to the Austrian economy as a whole and to the best possible healthcare provision. The performance of the industry is visualised at www.pharmastandort.at and the companies that work for Austria on a daily basis are shown.

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 2024



*for OTC products as of 25.06.2015

Source: PHARMIG, STATISTIK AUSTRIA, Österreichische Apothekerkammer, Österreichische Ärztekammer (18, 33, 34)

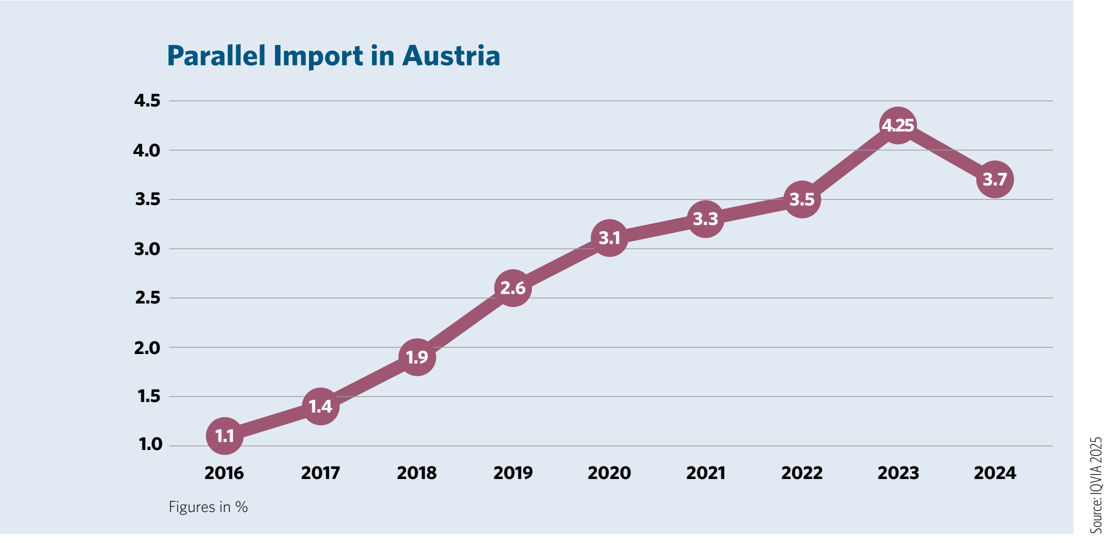
Around one third of the pharmaceuticals were sold to hospitals and two thirds to public pharmacies and the private practice sector (by value) in 2024.

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.

According to IQVIA, the share of sales accounted for by parallel imports has been rising steadily in Austria for several years: In 2024, this amounted to 3.7 % for the overall market. The private practice sector is significantly more affected with a share of 4.8 %. Compared to 1.28 % in 2015, the share of parallel imports has increased steadily in recent years. In 2024, the social insurance system issued a directive to additionally regulate the dispensing of parallel imported medicinal products in pharmacies in order to minimise financial disadvantages for the healthcare system (125). Parallel imports in the hospital market have tended to decline in recent years (1.7 % for 2024).



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 licence 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 Section 59a of the Medicines 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, (127)), 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 non-prescription 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).

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 (126). The notifications are published in the Distribution Restriction Register on the BASG website (medikamente.basg.gv.at) (114). Based on an evaluation scheme, the BASG subsequently also decides on a temporary parallel export ban for the reported products.

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

- Continued pressure on prices and consequently a migration of production to Asia as well as a concentration on a few manufacturers of active ingredients
- Unexpected demand that cannot be calculated in advance
- Shortages of components necessary for the production of a product (chemical components, intermediates, solvents, primary and secondary packaging)
- Quality problems in manufacturing (impurities in the production process, defects in packaging)
- Challenges in the field of logistics and storage
- Overall longer delivery times for components required in the manufacturing process (solvents and coatings, paper for packaging and package inserts, closures, plastic and glass containers)
- Ongoing shortage of skilled workers and staff shortages in production and logistics
- Incalculable outflows of goods abroad due to parallel trade (see Section 5.5)

Measures to reduce and avoid delivery delays are being implemented or discussed at the Austrian and European, system, and company level and are aimed at the following areas (129):

- **Increasing production capacity** on the part of pharmaceutical companies as far as possible
- **Establishment of national and European inventory** for certain medicines that are particularly relevant to the supply or increase of these inventories
- **Improved connection of the Sales Restriction Register** to the doctors' practice software
- **Regulatory flexibilities** with regard to the import (transfer) of medicinal products with foreign-language instructions.

- **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 (130).
- **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 (131).
- **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 ingredients with high volume and low complexity

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

According to § 25a AMG (71), speciality medicinal products to which non-safety-relevant changes have been made may now be placed on the market by marketing authorisation holders without this change until the respective expiry date of the speciality medicinal product – unless this is not justifiable for reasons of medicinal product safety. Previously, only pharmacies were authorised to do this. Marketing authorisation holders were previously only allowed to market packs that did not yet contain the change for one year.

The new § 6a AwEG 2010 (132) makes it easier to bring in proprietary medicinal products in the event of supply bottlenecks. The prerequisite is that the medicinal product has been authorised or manufactured in the EEA, that the demand cannot be met by a medicinal product that is authorised and available in Austria, that the medicinal product is needed to bridge supply bottlenecks and to ensure the supply to the patients.

The Austrian Stockpiling Ordinance was issued in June 2024 (133). From 21 April 2025, the respective marketing authorisation holder must stockpile the medicinal products listed in the annex to the ordinance in Austria. This applies primarily to prescription-only, off-patent human medicinal products that have been categorised as supply-critical within the meaning of this ordinance (see version as of May 2025 (128)). 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 be restored as quickly as possible.

The BASG provides practical information online in the form of a guide (134) and FAQs (135).

Marketing authorisation holders can generally claim reimbursement for additional costs incurred as a result of stockpiling. Details on this are regulated in Section 94k AMG.

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

6.18 Euros

in 2024.

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

2024 is +2.9 %.

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) and the General Social Insurance Act (ASVG for inclusion in the Reimbursement Code). The Price Commission of the Federal Ministry of Work, Social Affairs, Health, Care and Consumer Protection (BMASGPK) is responsible for setting the prices of medicinal products (137).

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

Factory/depot selling price (MSP/DAP): 10,- euros

Pharmacy purchase price (PPP): 11.25 euros
= MSP/DAP + wholesale mark-up

Gross RP: 15.20 euros
= PPP + pharmacy mark-up (excl. VAT **)

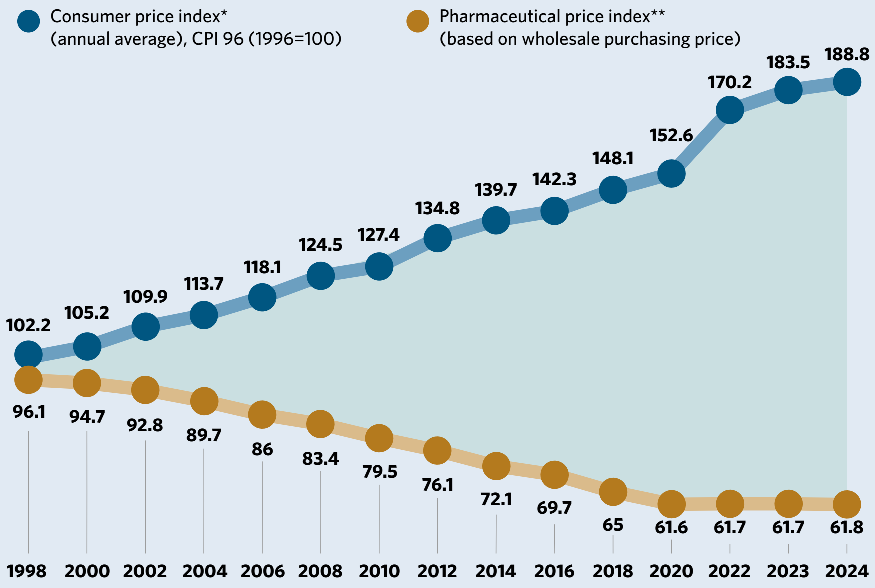
Net RP: 8.1 euros
= (PPP + pharmacy surcharge) – prescription fee* (excl. VAT **)

21.20 euros
= PPP + pharmacy surcharge + 15 % private sales surcharge (incl. VAT **)

*Prescription fee since 01.01.2025: 7.55 euros; **VAT since 01.01.2009: 10 %

Source : PHARMIG

Price trends (based on wholesale purchasing price)



*The consumer price index (CPI) is the standard index for general pricing trends and inflation in Austria.
The pharmaceutical price index (based on wholesale purchasing price) is based on IQVIA calculations and is an element of growth. The pharmaceutical price index incorporates changes in pricing (in %) of products which have already been placed on the market in comparison with the previous period.

Source: 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. A pack of medicine that cost 10 euros in 1996 only cost 6.18 euros in 2024. Due to legal regulations, automatic inflation adjustment is not permitted for medicinal products. Otherwise, the price of the fictitious medicine pack would have been 18.9 euros at the end of 2024. In 2024, the inflation/inflation rate was +2.9 % (138).

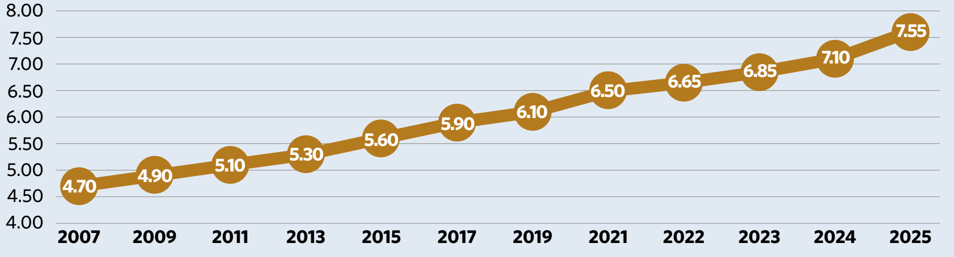
The consumer price index and the medicinal product price index diverge further from year to year. The price of medicines is falling continuously or stagnating, while the consumer price index is rising annually.

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) in 2024 (139).

* 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 (140). In the period 2007–2025, the prescription fee rose by around 61 %. In 2024, the prescription fee meant revenue of 492 million euros for the health insurance system (provisional budget 2024) (13).

Development of prescription fees 2007–2025



Values in euros

Source: Bundeskanzleramt Österreich (141)

In addition to the general exemption from the prescription fee for social reasons, there has been an annual prescription fee cap of 2 % of the insured person's annual net income (excluding special payments such as holiday or Christmas bonuses) since January 2008. If this threshold is exceeded, insured persons and co-insured relatives are exempt from the prescription fee for the remainder of the calendar year (142).

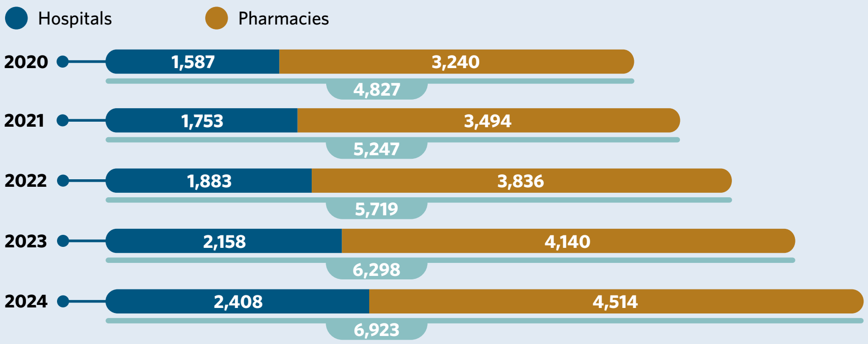
6.2 Hospital and Pharmaceutical Market

In 2024, the Austrian pharmaceutical market reached a value-based volume of 6.9 billion euros and a volume of 246 million packs.

This represents growth of +9.9 % in terms of sales and +1.6 % in terms of volume. From the perspective of manufacturers and distributors, the Austrian pharmaceutical market is divided into two segments:

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

Pharmaceutical sales (based on manufacturer price, MP*)



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

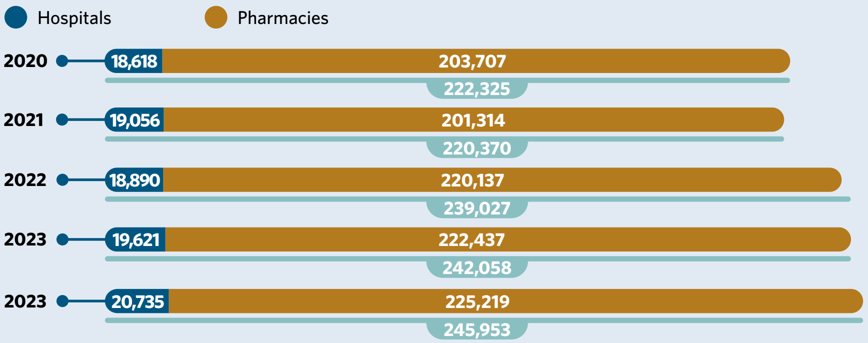
Source: IQVIA DPMÖ next level adaptierter Datenerfassung (inkl. RX Direktgeschäft)/ DPMÖK

Both the pharmacy market and the hospital market grew in terms of value and volume in 2024 compared to 2023.

- **Pharmaceutical market:** + 8.9 % by value in euros in turnover and + 0.9 % by volume by pack (public pharmacies).
- **Hospital market:** + 11,6 % in terms of value in euros in turnover and + 5.7 % by volume by pack.

In 2024 246 million packs were sold in Austria, 8 % of which went to hospitals (institutional pharmacies) and around 92 % to pharmacies in the extramural sector.

Sold packs



Figures in thousand packs

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

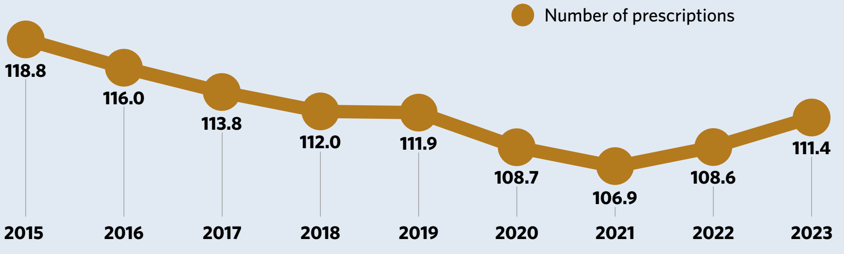
According to calculations by IQVIA, the growth of +9.5 % (measured in terms of sales in 2024) in the prescription-only market is influenced by a number of elements (IQVIA Elements of Growth Analysis 2025):

- **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 2024, price changes have a marginal impact on market development by 0.1 %.
- **New launches** include those products that contain new active ingredients in the first year after market launch. These products replace previous forms of therapy or enable new therapies for the first time. New launches will have a small impact on market growth of +0.5 % in 2024 – the same as in 2023.
- **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 2024, structural effects amounted to +8.9 %.

6.3 Prescription Trends

The number of prescriptions for therapeutic products decreased annually from 2014 to 2021. However, it has been rising slightly since 2022.

Number of Reimbursed Prescriptions per Insured Person

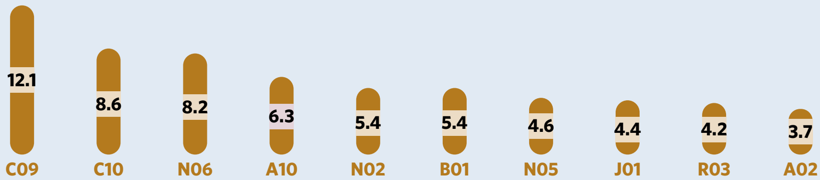


Figures in million euros

Source: Die österreichische Sozialversicherung in Zahlen 2025 (13)

6.4 Pharmaceutical Consumption by Indication Groups

The most frequently prescribed therapeutic subgroups ATC-level 2*, 2023



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

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

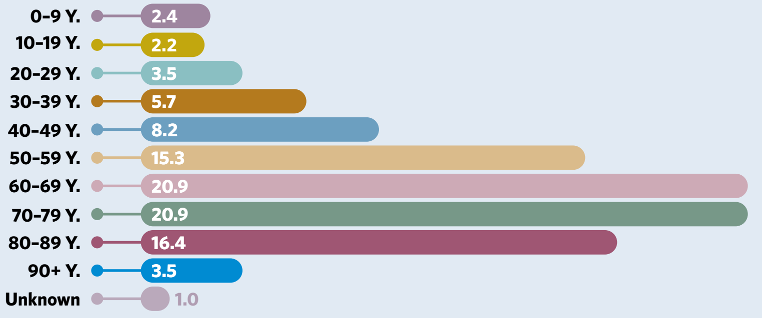
Source: Die österreichische Sozialversicherung in Zahlen 2025 (13)

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: Medicinal products with an effect on the renin-angiotensin system (e.g. for high blood pressure), psychoanaleptics (for mental illnesses, e.g. depression) and medicinal products that influence lipid metabolism. These three indication groups with the highest number of prescriptions account for just under 26 % of all prescriptions (13).

6.5 Pharmaceutical Requirements by Age

Pharmaceutical needs in 2024 in %
(Patients with statutory health insurance, by packs)

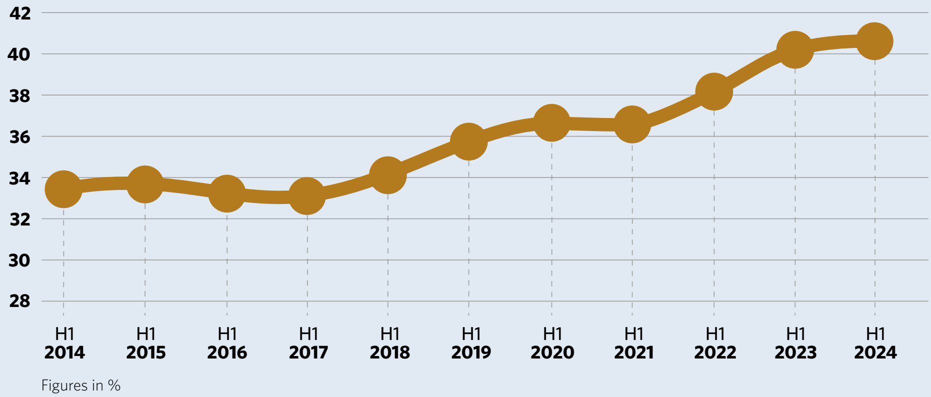


Source: Apothekerkammer Österreich (143)

The need for medicinal products also increases sharply from the age of 50. The need of all people aged 60 and over is 61.7 % (143).

6.6 Generic Medicinal Products

Prescribed generic products in the reimbursement market



Figures in %

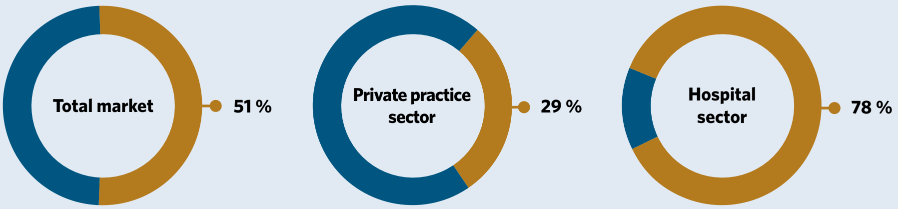
Source: Österreichische Sozialversicherung, Allgemeines aus dem Erstattungskodex (EKO) (144)

In the first half of 2024, generics accounted for over 40% of all dispensed packs in the registered market. If only the available market is considered, the share of generics was 61.19 % in 2024, i.e. more than every second package dispensed was a generic (145) (see also Sections 3.2 and 7.3).

6.7 Biosimilars

At the end of 2024, 59 authorised biosimilars (for 19 different active ingredients) 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 96 biosimilars for 26 active pharmaceutical ingredients (as of 12/24) (146).

Biosimilars accounted for 51% of the total possible biosimilar market in Austria (in terms of sales) in 2024: In the private practice market, this share is around 29% and in the hospital market 78%.



Figures in %

Source: Biosimilarsverband Österreich (146)

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

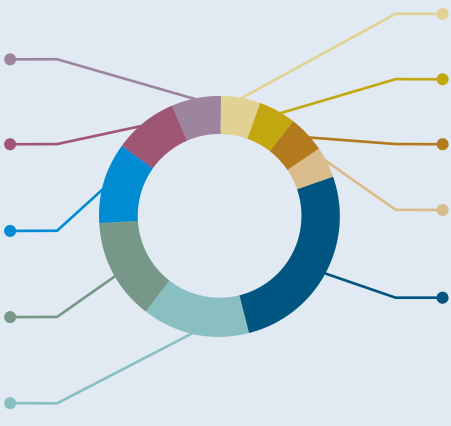
The introduction of biosimilars and the associated price reductions of reference medicines in the retail and hospital sectors have resulted in savings of around 1.18 billion euros (MSP) over the last 14 years. A further considerable savings potential of around 330 million euros (MSP) can be realised for Austria by 2027 (consumption and price simulation study) (147).

6.8 Self-medication Market

The OTC market grew by +3.5% in value terms in 2023 compared to 2022 to € 1,525 million (AVP). The average growth since 2021 is 6.2% per year. In terms of volume, after an increase of 9.6% in 2022, there was a decline of 0.3% in 2023 and 0.5% in 2024. (148).

Drugs for the treatment of coughs and colds continued to be the largest indication group in 2024 with a share of 24.3 % (measured in terms of sales in AVP). The growth rate compared to 2022 is +3.9 %. Products for the digestive system, which occupy second place in the sales statistics, recorded the highest increase with growth of 7.9 % (148).

Indication groups in self-medication (basis AVP) 2024



Figures in %

Source: IGEPHA Jahresbericht 2024

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 convince with their

Benefits and costs.

7. Reimbursement of Pharmaceuticals by Social Security

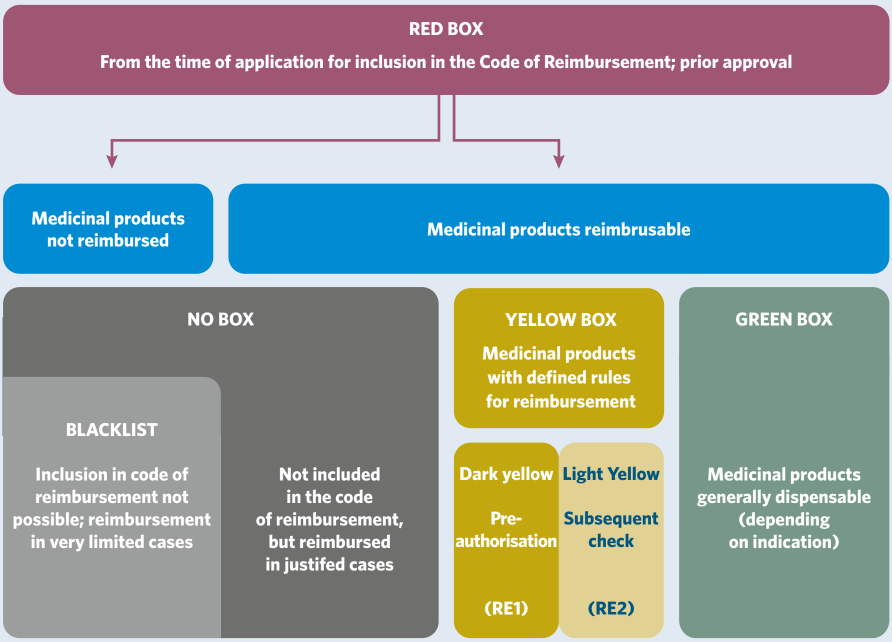
The majority of social security benefits are subject to the principle of benefits in kind. The scope of medical treatment at the expense of social security is defined by law as follows: "It must be sufficient and expedient but must not exceed what is necessary." (§ 133 ASVG)

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 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) – in other words, they are convincing both in terms of their benefits and in terms of costs. On 1 January 2005, the Reimbursement Code replaced the list of therapeutic products used until then (149).

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

The box system – simplified presentation



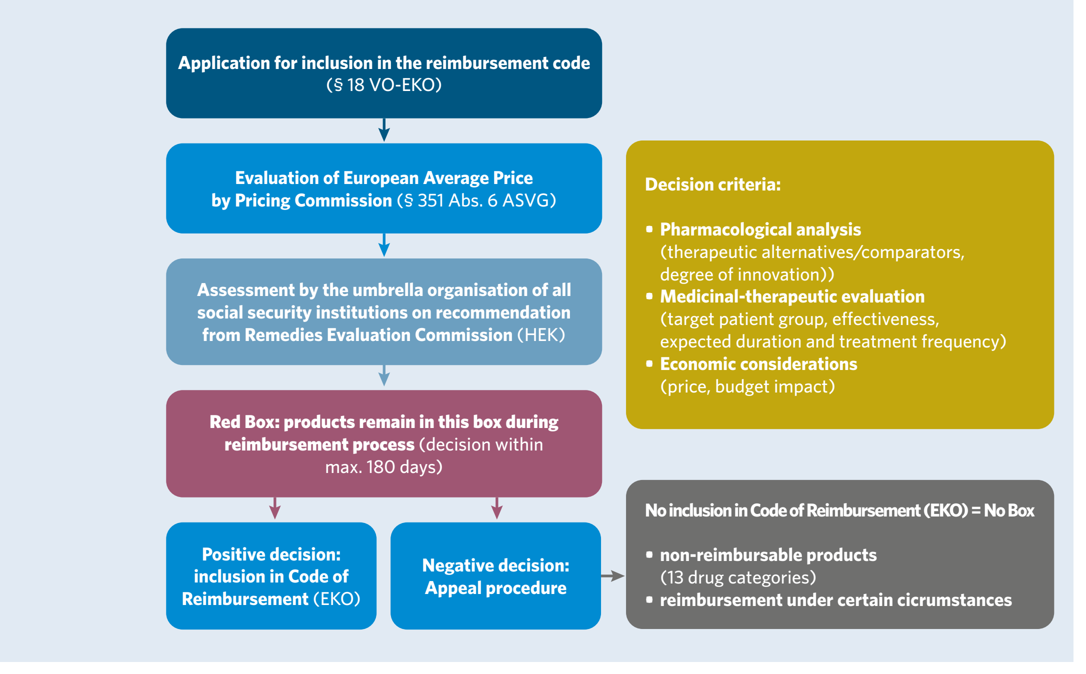
Source: FOPI – Erstattungskodex (EKO) und Arzneimittel-„Boxensystem" (150)

- **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 specialty medicinal product applied for, added therapeutic value must be demonstrated.
- **The yellow box** includes those medicinal products that have a significant additional therapeutic benefit for patients and that have not been included in the green area for medical and/or health economic reasons. For a medicinal product in this area, a maximum of the EU average price determined may be charged. The costs will only be covered by the health insurance institutions if the medical 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 organisation 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 proprietary medicinal product must not exceed the EU average price. The costs are only covered by the health insurance institutions if they have been approved by the chief and control medical service of the social insurance system.

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

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

On the basis of the ASVG (§ 351c ff.), the Rules of Procedure for the Publication of the Reimbursement Code (VO-EKO) regulate in detail the process, the requirements and the deadlines for the inclusion of medicinal products in the Reimbursement Code. The admission procedure is an administrative procedure and is carried out by means of an electronic application. The medicinal products contained in the Reimbursement Code are published at the beginning of each year in printed form and as downloads (153), and the monthly changes are published on the internet under www.ris.bka.gv.at (154).



Source: Österreichische Gesundheitskasse, Arbeitsbehelf Erstattungskodex (155)

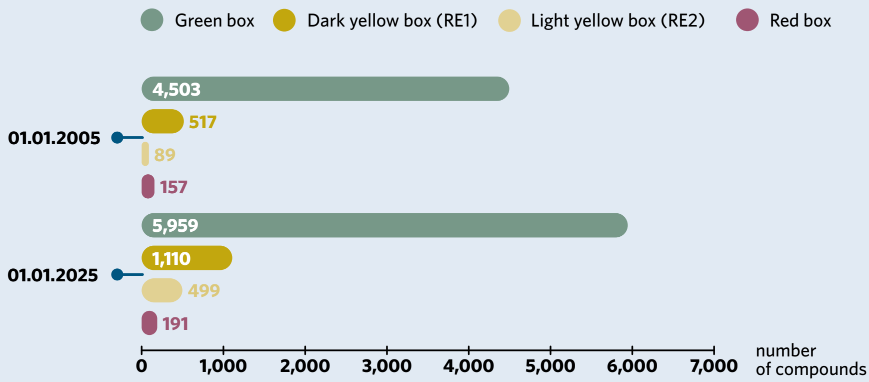
Certain groups of medicinal products are generally excluded from inclusion in the EKO (Official Announcement No. 34/2004; list of non-reimbursable categories of medicines in accordance with § 351c (2) ASVG) and must usually be paid for by the patients themselves, unless the assumption of costs has been approved in advance by the chief medical service (e.g. medicines that are mainly dispensed in hospitals, contraceptives, etc.) (155).

Remedies Evaluation Commission (HEK)

The Remedies Evaluation Commission is the advisory body of the umbrella organisation 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.

The members of the Remedies Evaluation Commission and their deputies can be found on the website of the Austrian Social Insurance (156).

Number of medicinal products in the EKO*



The data was taken from the list of goods published by the Austrian Chamber of Pharmacists | as of 01.01.2025
*by the package – pharmaceutical registration numbers

Source: Dachverband der Sozialversicherungsträger (157)

As of 1 January 2025, a total of 7,759 packs were listed in the EKO, compared to 5,266 packs when it was introduced in 2005.

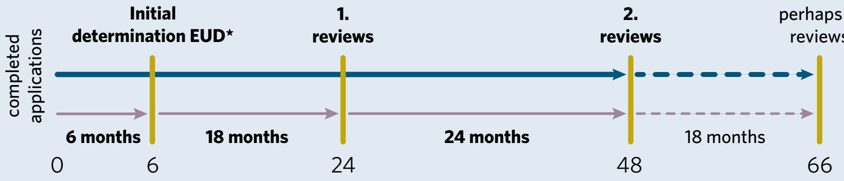
7.3 Specific Price Regulations Through Social Insurance

EU Average Price

As part of the 61st ASVG amendment, the EU average price was newly regulated as the maximum limit for reimbursement prices. The Price Commission of the Ministry of Social Affairs 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.

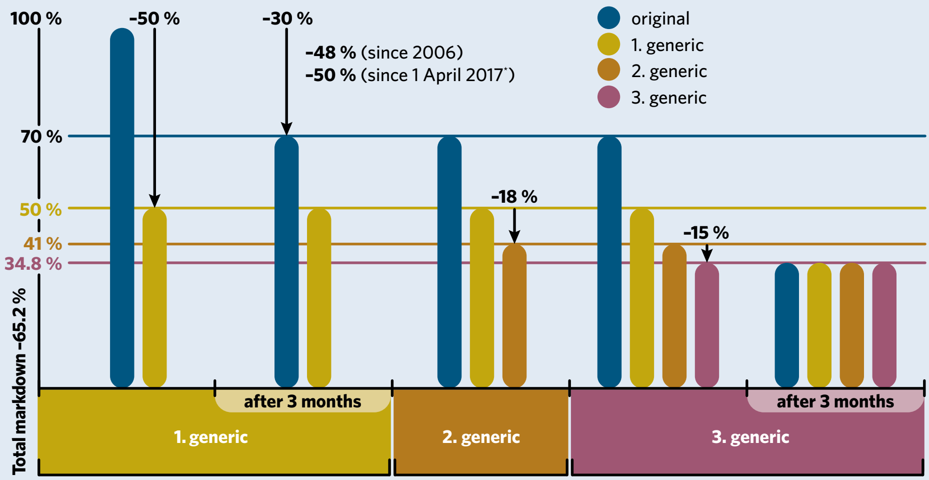


*EUD= EU average price

Source: Österreichische Gesundheitskasse – Arbeitsbehelf Erstattungskodex (155)

Generic Medicinal Products

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

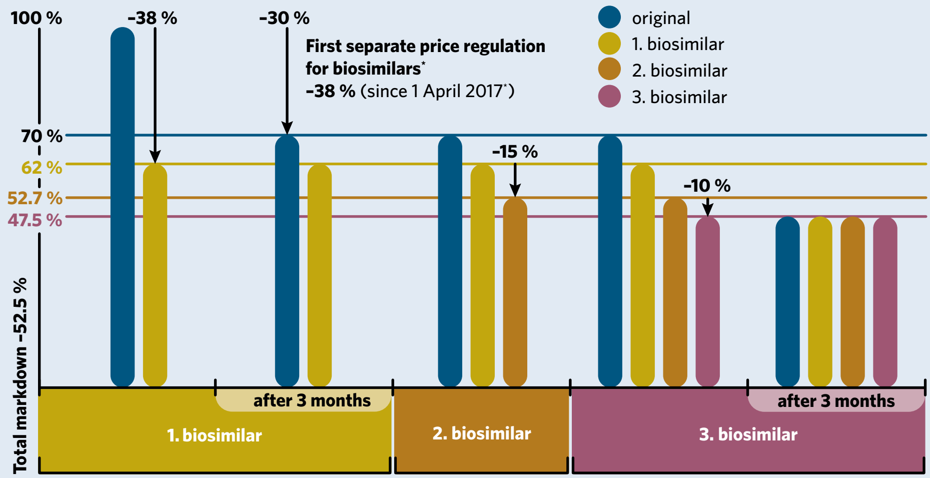


*ASVG amendment from BGBl. No. I, 49/2017 § 351c Para. 10 in force as of 1 April 2017, limited until 31 December 2023

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

Biosimilars

With the 2017 amendment to the ASVG, a separate price regulation for biosimilars was laid down in the ASVG for the first time (§351c para. 10 Z2 ASVG, for biosimilars see also Section 3.1), 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 2023

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

Price Range

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

In 2023, a new, adapted application was made with a price corridor of up to 20% to the cheapest speciality medicinal product with the same active ingredient in the same or practically the same dosage form. The decisive factor within an active ingredient is the respective key strength (the most frequently prescribed). The price reduction is limited to the amount of the prescription fee, i.e. speciality medicinal products whose price is below the prescription fee are excluded from this regulation. However, these are used to determine the maximum price. In return, the cancellation procedure will no longer apply to these products until 31 December 2023 for economic reasons.

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

According to the social insurance organisation, the savings from the price band in 2017, 2019 and 2021 amounted to around 74 million euros. According to I QVIA's calculations, social insurance can expect savings of more than 90 million euros for 2023 alone as a result of the changed mode (based on cash selling price (KVP), list prices, sources: Parliamentary enquiry response 8908/AB, IQVIA).

Source: Parlamentarische Anfrage-beantwortung 8908/AB, IQVIA

Special Provisions for Proprietary Medicinal Products Outside the EKO ("No box")

The special provisions (§ 351c (9a) ASVG) that have been in force since the 2017 amendment to the ASVG for proprietary medicinal products that are not listed in the EKO (see 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 FAP offset against social security exceeds the EU average price, there is an obligation to repay these proprietary medicinal products in excess of the difference (155).

Price Increases

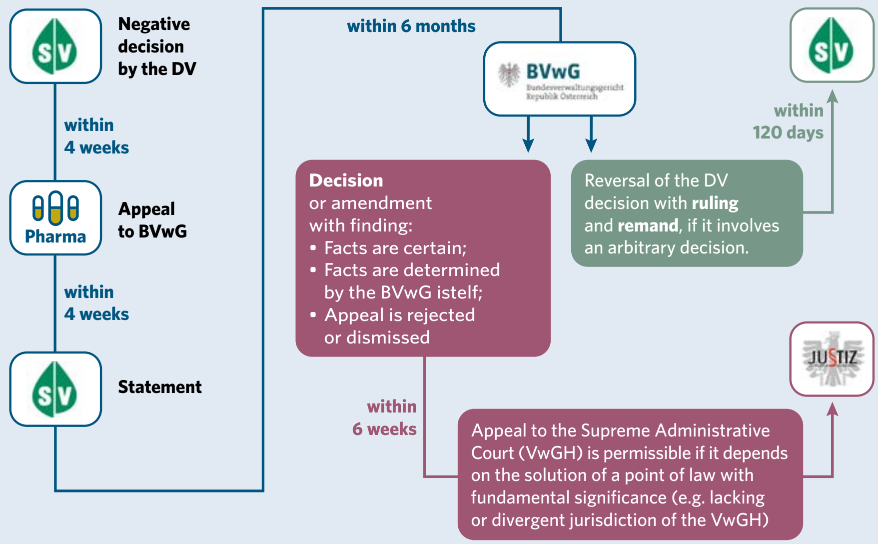
Price increases for medicinal products are regulated by law in a very restrictive manner (e.g. max. every 24 months) and are only possible to a very limited extent. The umbrella organisation has a wide margin of discretion in this regard (155).

7.4 Federal Administrative Court

The Federal Administrative Court (BVwG) is responsible for appeals against a decision of the umbrella organisation 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) (158).

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.

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 (159) and the European EFPIA Code of Practice (160), 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 (161).

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 (162).

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 (163)(see also Section 2.6).

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:

- Directive on corporate sustainability reporting (CSRD) (164)
- Directive on the due diligence obligations of companies with regard to sustainability (CSDDD, so-called EU Supply Chain Directive) (165)
- Regulation on fluorinated greenhouse gases (F-Gas Regulation) (166)
- Packaging and Packaging Waste Regulation (PPWR) (167)

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 (168), the EU's so-called chemicals regulation (169, 170). The ECHA has not yet made a decision.

8.3.1 Municipal Wastewater Directive (KARL)

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 municipal wastewater (KARL, UWWTD) (171) 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 for 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, approval 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 Security Act **(Allgemeines Sozialversicherungsgesetz – 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 organisation 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
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
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

Law	Regulatory Areas
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
Directive (EU) 2019/1937 on corporate due diligence in respect of sustainability **(CSDDD)**	EU Supply Chain Directive - Corporate due diligence in the areas of human rights and environmental protection along the value chain
Directive (EU) 2022/2464 on corporate sustainability reporting **(CSRD)**	Reporting in accordance with the European Sustainability Reporting Standards (ESRS)
Directive (EU) 2024/3019 on the treatment of municipal wastewater **(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
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

Law	Regulatory Areas
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 (EU) 2025/327 on the European Health Data Space **(EHDS)**	Establishment of the European Health Data Space (EHDS)

Other Regulations		Regulatory Areas
Good Manufacturing Practices	GMP	Guidelines for the manufacturing of medicinal products
Good Distribution Practices	GDP	Guidelines for medicinal product logistics
Good Pharmacovigilance Practices	GVP	Guidelines for pharmacovigilance
EFPIA Code of Practice		Ethical rules agreed by EFPIA members for the advertising of medicinal products to healthcare professionals
IFPMA Code of Practice		Framework for compliance with regulations for clinical research, fees for services, support for medical training
PHARMIG 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

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10. Abbreviations

Abbreviation	Definition | A–F
AEP/PPP	Pharmacy Purchase Price
AMBO	Pharmaceutical Operating Regulations
AMDC	Austrian Micro Data Center
AMG	Medicines Act
AMR	Antimicrobial Resistances
AMVO	Austrian Medicines Verification Organisation
AMVS	Austrian Medicines Verification System
ASVG	General Social Insurance Act
ATMP	Advanced Therapy Medicinal Products
AUVA	General Accident Insurance Institution
AVP	Pharmacy Sales Price
AwEG	Medicinal Products Import Act
BASG	Federal Office for Safety in Health Care
GDP	Gross Domestic Product
BMASGPK	Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection
BVAEB	Insurance Institution for Public Employees, Railways and Mining
B-VG	Federal Constitutional Law
BVerG	Federal Procurement Act
CHMP	Committee for Medicinal Products for Human Use
COVID	Corona Virus Disease
CSDDD	Directive on the due diligence obligations of companies with regard to sustainability
CSRD	Guideline on sustainability reporting by companies
CTCG	Clinical Trials Coordination Group
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation
DAP/DSP	Depot Sales Price
DCP	Decentralised procedure
DVSV	Umbrella organisation of social insurance institutions
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
EVPM	EudraVigilance post-authorisation module
EWR/EEA	European Economic Area
F&E/R&D	Research & Development
FTE	Full Time Equivalent

Abbreviation	Definition | F–P
FAP/MSP	Manufacturer Sales Price
FDA	U.S. Food and Drug Administration
GDP	Good Distribution Practices
GESG	Health and Food Security Act
GMP	Good Manufacturing Practice
GÖG	Health Austria Company (Gesundheit Österreich GmbH)
GVP	Good Pharmacovigilance Practices
HEK	Therapeutic Products Evaluation Commission
HPV	Human Papilloma Virus
HTA	Health Technology Assessment
ICH	International Conference on 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
KAKuG	Hospitals and Health Resorts Act
KARL	Municipal wastewater guideline
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
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 Institute of Health
NIS	Non-interventional study
NKSE	National Coordination Centre for Rare Diseases
OD	Orphan Drugs
OECD	Organisation for Economic Cooperation and Development
ÖGK	Austrian Health Insurance Fund
ÖVIH	Austrian Association of Vaccine Manufacturers
OTC	Over The Counter
PASS	Post-authorisation safety study
PFAS	Per- and polyfluorinated alkyl substances
PHAGO	Association of Austrian Wholesalers of Medicinal Products

Abbreviations	Definition | P–W
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
QP	Qualified Person
RD	Rare Diseases
RDP	Regulatory Data Protection
RSV	Human respiratory syncytial virus
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
UNEP	United Nations Environment Programme
Ust./VAT	Value added tax
UWWTD	Urban Waste Water Directive
VHC/CoC	PHARMIG Code of Conduct
VO/Reg	Regulation
VO-EKO	Rules of procedure for issuing the reimbursement code pursuant to Section 351g ASVG
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation

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