GLOBAL LEGAL INSIGHTS

PRICING AND REIMBURSEMENT 2024, 7TH EDITION

CHAPTER TEMPLATE AUSTRIA

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Abstract

The pricing and reimbursement of medicinal products (meaning medicines for human use) is not harmonised under EU laws; the reimbursement and pricing of such products are thus subject to various national regulations and healthcare systems which differ considerably from each other. While legislators and stakeholders in healthcare must, on the one hand, strive to incentivise pharmaceutical innovation, at the same time, they must also maintain a healthcare system that is accessible and affordable for patients, stakeholders and the state. To this end, EU Member States, including the democratic Republic of Austria (Austria), have adopted regulations and systems to ensure accessibility and innovation and limit public expenditures in the form of pricing and reimbursement rules for healthcare products.

In Austria, the pricing and reimbursement of medicinal products is subject to a complex and fragmented regulatory framework. Generally speaking, medicines purchased by patients (outpatient sector) that are listed in the so-called Austrian Reimbursement Code (*Erstattungskodex* – EKO) must be reimbursed to the patients by the Austrian social security carriers (minus a fixed prescription fee), whereas the pricing and reimbursement of medicines administered in hospitals or practices (inpatient sector) largely depends on contractual arrangements between social security carriers and the healthcare sector. The outpatient sector roughly accounts for two thirds of the total market for prescription drugs. Also, the prices of medicines in this segment cannot be freely set but are subject to an external price referencing (EPR) system based on EU average pricing.

The following exclusively discusses the pricing and reimbursement of medicinal products; different rules apply with regard to the pricing and reimbursement of medical devices and other healthcare products.

Market introduction/overview

Austria is a landlocked state in Central Europe; it is bordered by eight European countries, namely: Switzerland and Liechtenstein to the west; Germany to the northwest; the Czech Republic to the north; Slovakia to the northeast; Hungary to the east; as well as Italy and Slovenia to the south. Austria is an EU Member State, and is a federation of nine federal states, with the City of Vienna being the capital and a federal state of its own.

As of April 2024, Austria has 9,170,647 inhabitants; population growth in Austria is expected to increase sharply due to migration flows (2050: approx. 9.85 million inhabitants).[1] The proportion of people aged over 65 is expected to continue to rise and reach 27.9% in 2050.[2]

The Austrian healthcare system is characterised by the country's federal structure and is fragmented.[3] Due to the large number of stakeholders and decision makers (federal government, provinces, municipalities, social insurance), the financing of healthcare is not centrally regulated, but comes from various sources, namely taxes, social insurance contributions via the social insurance,

federal government, provinces and municipalities. All insurance providers are combined in an umbrella organisation, namely the Austrian Federation of Social Insurance Providers (*Dachverband der Sozialversicherungsträger – Dachverband*), which is the main decision maker in the field of pricing and reimbursement of medicines for the outpatient sector. Austrian social insurance consists of five insurance institutions: the Austrian Health Insurance Fund (*Österreichische Gesundheitskasse – ÖGK*); Pension Insurance Institution (*Pensionsversicherungsanstalt*); the Social Insurance Institution for the Self-Employed (*Sozialversicherungsanstalt der Selbstständigen*); the Insurance Institution for Public Employees, Railways and Mining (*Versicherungsanstalt öffentlich Bediensteter, Eisenbahnen und Bergbau*); and the General Accident Insurance Institution (*Allgemeine Unfallversicherungsanstalt*).

Austrian social insurance includes health, pension and accident insurance. There is compulsory membership of the respective nationwide professional insurance or the ÖGK. Statutory health insurance allows multiple insurance. With 7.5 million insured persons (82% of the Austrian resident population), ÖGK is the largest statutory health insurance scheme in Austria.[4]

Austria's healthcare expenditure amounted to EUR 52.28 billion in 2023, which roughly corresponds to 10.9% of gross domestic product. Compared to 2022, this expenditure increased by 4.8%.[5] More than three quarters of expenditure is financed by public funds. In 2023, the federal government, provinces, municipalities and social insurance institutions accounted for EUR 40.33 billion (77.1%) of the current healthcare expenditure, which corresponds to an increase of 4.2% compared to 2022. Current healthcare expenditure by private households, voluntary health insurers, private non-profit organisations and companies amounted to EUR 11.9 billion or 22.9% of current healthcare expenditure. Private current expenditure therefore increased by 6.7% from 2022 to 2023.[6]

Around EUR 16.6 billion will be spent on research and development in Austria in 2024 as per estimates by Statistics Austria.[7] Companies account for the largest share of total research expenditure at 51%, 34% is borne by the public sector and 16% by foreign countries.[8]

Austria is an export country and sports a positive trade balance in the pharmaceutical (medicinal products) industry. Austria-based pharmaceutical companies, which either manufacture medicinal products themselves or import end-released drugs into Austria, vary greatly in their business volume. Next to international pharmaceutical groups and corporations, the corporate landscape is dominated by small and medium-sized enterprises. Sales can range from a few thousand euros to EUR 250 million per year.[9]

In 2024, approximately 16,112 approved medicines for human use exist in Austria, 25% of which are available over-the-counter (OTC) in pharmacies. The following three indication groups account for 26% of all prescriptions: drugs for high blood pressure; mental illnesses; and drugs that affect fat metabolism. In the last five years, a total of 201 medicinal products with new active ingredients have been approved in Austria, 36 of which were approved in 2023. The new market approvals are for the treatment of cancer, hematological diseases, diseases of the central nervous system, the cardiovascular system and metabolism.[10]

Prices of medicinal product on the Austrian market have fallen since 1996.[11] A medicine pack that cost EUR 10 in 1996 cost only EUR 6.17 in 2023. However, the Austrian consumer price index is developing in the opposite direction as inflation was 7.8% in 2023. The Austrian pharmaceutical market reached a value volume of EUR 6.3 billion in 2023 (+10.1% compared to 2022) and a volume of 242 million product packs (+1.3% compared to 2022); 8% of the products were sold to hospitals and 92% to pharmacies.

The OTC drug market grew by 6.5% to EUR 1,471 million (pharmacy sales price) in 2023 compared to 2022.[12] In terms of volume, after an increase of 9.4% in 2022, there has been a decrease of 0.2% in 2023. Medicines for the treatment of coughs and colds further represented the largest indication group in 2023 with a share of 24.1%. The growth rate compared to 2022 is +6%. The group of preparations for ophthalmology (eye medicines) showed the strongest growth at 11.3% in 2023.

In Austria, price-link regulations (see below) on generics and biosimilars exist that have resulted in significant price reductions for original drugs.[13] In the first half of 2023, generics accounted for more than 40% of all prescriptions dispensed in the outpatient market. When only considering the market of reimbursable medicines, the share of generics is 59.9%. At the end of 2023, 55 approved biosimilars were available in Austria for the treatment of diseases such as cancer, autoimmune diseases, growth disorders, osteoporosis and blood coagulation. Biosimilars accounted for 64.28%

of the total biosimilar market in Austria in 2023. In the private practice (outpatient) market, this share is around 41% and in the hospital (inpatient) market it is 87%.

Pharmaceutical pricing and reimbursement

With regard to pricing and reimbursement, the inpatient and outpatient sectors must be distinguished; only the latter is subject to regulated procedures.

Outpatient reimbursement system (EKO procedure)

Generally, the scope of medical treatment at the expense of Austrian social security is legally defined as follows: "The medical treatment must be sufficient and purposeful but shall not go beyond what is necessary."[14] Thus, remedies for medical treatments are all means that serve to eliminate or alleviate an illness or to ensure the success of the treatment, but excluding such health products that are part of everyday life (e.g. fever thermometers, herbal teas, etc.). This includes all necessary medicines ("*Arzneien*")[15] which essentially are all agents that act on the internal organism by being administered to it in an appropriate manner or by influencing local diseases of the skin or mucous membranes.[16] This corresponds with the legal definition of medicinal products under European and Austrian regulations (including pharmacy preparations),[17] with the possible exception of drugs that do not serve medical treatment, e.g. diagnostical or preventive drugs.

The outpatient pricing and reimbursement of medicines that are prescribed by a physician and then dispensed by a pharmacy is governed by a regulated procedure subject to the relevant medicine being listed in the EKO issued by the Dachverband. Therefore, only such medications that have been included in the EKO can be prescribed at the expense of the health insurance companies – exceptions of this general rule are only possible in medically justified individual cases.

By way of background, the EKO was first published by the legal predecessor of Dachverband (the Main Association of Social Insurance Institutions) in 2005 as the successor of the previous drug reimbursement list (*Heilmittelverzeichnis*). As of January 1, 2024, a total of 7,720 medicines (packages with a pharmaceutical registration number) were listed in the EKO, compared to 5,266 packages when the EKO was originally introduced.[18] The EKO is published at the beginning of each year (in printed form) and contains the green and yellow boxes (see the table below). Changes (including the red box) are published monthly on the internet.[19]

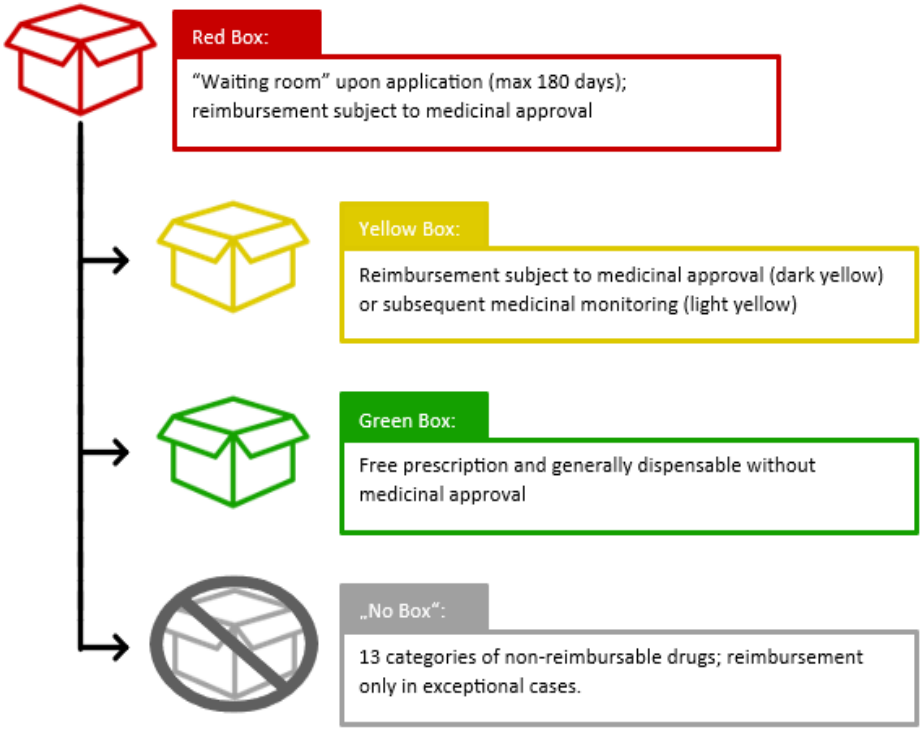
The EKO includes medicinal products that are authorised, reimbursable and available for delivery in Austria,[20] and that, based on international experience and the current state of science, have a therapeutic effect and benefit for patients in the sense of medical treatment;[21] as mentioned before, the medical treatment must be sufficient and appropriate, but must not exceed what is necessary.

Dachverband can initiate an EKO procedure for a medicine itself. However, usually pharmaceutical companies/entities, typically the market authorisation holder or a pharmaceutical wholesaler authorised to sell a relevant medicinal product, will apply for admission to the EKO. The medicinal products are checked for their eligibility for reimbursement and subjected to a comprehensive health technical assessment (HTA) that involves pharmacological, medical-therapeutic and health economic evaluations (see below for further details). The Dachverband is supported by an independent and non-directive advisory body – namely the Medicinal Products Evaluation Commission (*Heilmittel Evaluierungs-Kommission* – HEK) – on the basis of whose recommendations the Dachverband renders its decisions.

Moreover, changes to the prescription status and any deletions from the EKO can be effected upon application of the pharmaceutical entity authorised to sell, or at the instigation of the Dachverband based on recommendations by the HEK.

EKO box system

The EKO includes the allocation of medications into a box system and their classification using the ATC code (anatomical-therapeutic-chemical classification system). In a nutshell, the box system is divided into three areas: green; yellow; and red boxes.



The Green Box area: This contains medicinal products that can be dispensed, either generally or under certain conditions, in the quantity specified as freely prescribable without the approval of the chief medical and controlling service (*chef- und kontrollärztlicher Dienst*) at the social security institutions. Thus, this area includes such medicines that can be dispensed without further authorisation as the dispensing is *per se* deemed medically and health-economically reasonable. The inclusion of medicinal products in this box area may also refer to certain uses, such as groups of diseases, medical specialty groups, age groups of patients or dosage form.[22]

The Yellow Box area: This area includes medicinal products that have a significant additional therapeutic benefit for patients, and that have not been included in the green area of the EKO for medical and/or health economic reasons. In order to be reimbursed, there is an additional requirement of prior authorisation or subsequent control. Accordingly, the Yellow Box is distinguished between two subdivisions, namely: the so-called Dark-yellow Box area; and the Light-yellow Box area.

- Dark-yellow Box (also known as RE1): The costs will only be covered or reimbursed if there is prior approval from the health insurance's chief medical officer and control medical service (control physician).

- Light-yellow Box (also known as RE2): In this area the prescribing physician (not the control physician) must prove and document compliance with a specific use (indication) required for the respective medication. Compliance with the specific use based on the documentation is subject to subsequent control by the health insurance company (*ex-post* control regime).

The Red Box area: This temporarily contains medicinal products for which a complete application for inclusion in the EKO has been submitted, until Dachverband has made a final (legally binding) decision on the application. In other words, this is the EKO's waiting room; as per statutory and European law requirements,[23] this process may not take longer than 180 days as from filing the application. However, the reimbursement of a drug is even possible in the Red Box area. The costs for medications will only be reimbursed if no alternative therapy in the EKO is sufficient and if there is prior approval from the health insurance company's chief medical officer and control medical service (control physician). The Red Box is published exclusively on the internet.

The "No-Box" area: This area means medicines that are not included in the EKO, respectively, are generally not reimbursable.[24] There are several types of medicinal products that are *per se* not

suitable for reimbursement and inclusion in the EKO.[25] These not-reimbursable medicines (currently 13 categories) are listed in the list of non-reimbursable medicinal product categories and, *inter alia*, include drugs mainly for hospital use, medicines for prophylaxis, contraceptives, medicinal products with predominantly cosmetic effect and, weight- loss drugs.[26] This list includes products for which the therapeutic effect has not been sufficiently proven and thus primarily improve the quality of life (lifestyle products). In justified individual cases, drugs falling into a category of this list can be reimbursed subject to approval of the chief medical officer and control medical service (control physician).[27] These medicinal products can also be included in the EKO if it is clear from the documents submitted by the applicant that the medicinal product is nevertheless suitable for treating the patient.[28]

Furthermore, medicinal products that are not approved in Austria, as well as medicines that are just not listed in the EKO, can be reimbursed as well; the former applies if treatment with approved medicinal products is not available or has been unsuccessful according to the recognised rules of medical art and the treatment with the non-approved medication was actually successful or the treatment was promising based on the results of a certain number of cases (sufficient to form a set of experience). As to the latter category, the chief medical officer or controlling medical service can authorise the prescription of a medicinal product that is not listed in the EKO if the treatment is necessary in the individual case for compelling therapeutic reasons and no listed medicinal product is available.[29]

For the sake of good order, ingredients for magistral preparations that are listed in the Austrian Pharmacopoeia are considered part of the Green Box, unless they are expressly listed in the Yellow Box based on a recommendation by the HEK.[30]

Overview on health technology evaluations

As soon as a medicinal product is listed the Red Box, Dachverband will check whether the drug can be included in the Green Box or Yellow Box. To do this, the medicine must have a certain added value compared to medicinal products already listed in the EKO. This added value can be a price difference compared to other listed products,[31] or in a medical-therapeutic advantage.[32] The pharmaceutical company must submit pharmacological, medical therapeutic and health economic documents.[33]

(i) Pharmacological evaluation

The pharmacological evaluation checks to what extent the drug in the Red Box represents a therapeutic alternative to the drugs already listed in the EKO.[34] The degree of innovation must be checked, for example based on the active ingredient, potency, combination of active ingredients and dosage forms, or whether the treatment of a disease is possible for the first time ever or for the first time with medication.

The degree of innovation is essential and must be determined via the following eight statutory standards:[35] the medicine has (i) the same active ingredient, same strength and practically the same pharmaceutical form as one or more previously EKO-listed medicinal products; (ii) the same active ingredient and essentially the same pharmaceutical form, but has a new strength; (iii) a new combination of active ingredients already listed; (iv) a new pharmaceutical form of already listed ingredients; (v) a new active ingredient belonging to an already listed therapeutic group with a uniformly defined active principle; (vi) a new active ingredient with a new active principle for treating an illness for which treatments are already listed; (vii) the medicine sports a new active ingredient providing first-time treatment with a medicine for an illness previously treated otherwise; or (viii) enables the first-time treatment of a disease.

(ii) Medical-therapeutic evaluation

The medical-therapeutic evaluation assesses which patient groups the medicinal product should be used for, and what therapeutic benefits the drug brings in comparison to the other therapeutic alternatives.[36] This information must be checked for its internal and external validity using pharmacoeconomic studies, with the law setting forth an explicit ranking for the validity of the evidence.

As part of an overall assessment, the new medication is to be assigned to one of the six legally defined groups according to its degree of therapeutic benefit: (i) no added therapeutic value, because the new medicine is essentially the same as medicinal products already on the list; (ii)

further therapeutic option with similar benefit as medicinal products already on the list; (iii) added therapeutic benefit for a subgroup of patients who may be treated with the new medicinal product; (iv) added therapeutic benefit for the majority of patients; (v) substantial added therapeutic benefit for a subgroup of patients; or (vi) substantial added therapeutic benefit for the majority of patients.

With regard to clinical studies, it must be stated whether it is a key study (e.g. "pivotal study" – a maximum of three studies can be described as such); otherwise, a review article evaluating the individual studies and a meta-analysis carried out in accordance with the current state of science are required.

(iii) Health economic evaluation

The health economic evaluation is an economic cost-benefit analysis with included price comparison, and is based on the results of the medical-therapeutic evaluation.[37] It must be assessed whether the new medicine provides for an economical treatment alternative compared to the drugs already available in the EKO. A price change or discount must then be applied depending on the additional benefit compared to the comparison products.

In the course of the assessment, it must be taken into account whether the cost-benefit ratio of the new medicine is justifiable in health economic terms. When evaluating the cost-benefit ratio, the direct costs of compulsory services provided by social insurance providers for medical treatment (medical assistance, medicines, medical devices), institutional care and medical rehabilitation measures are to be calculated on the basis of the prices actually charged; any cost contributions by patients (in particular deductibles, prescription fees or treatment contributions) are to be disregarded.

The law also sets out criteria and requirements for assessing the economic viability for inclusion in the Green and Yellow Boxes.[38]

<u>EKO prescription rules</u>

A "traffic light principle" applies: Green before Yellow; and Yellow before Red Box. Therefore, before prescribing a medicinal product in the Red Box, it must be checked whether prescribing a medicine from the Green or Yellow area of the EKO would not be more expedient and economical. Moreover, before prescribing a medicinal product from the Yellow area of the EKO, it must be checked whether prescribing a medicinal product from the Green area of the EKO would not be more expedient and economical.

The ranking within the individual areas is based on the ATC code. Within an ATC code, the active ingredient strengths are ranked in ascending order and within a strength they are separated according to dosage form. The following ranking criteria are used: (i) ATC code; (ii) active ingredient strength or combination of active ingredients with identical composition; and (iii) same or comparable dosage form.

In the comparison groups created in this way, the medicinal products are arranged alphabetically. For medicinal products in such a comparison group, therapeutic equivalence can generally be assumed, but the individual indication must be taken into account when prescribing. The most cost-effective medicinal product in a comparison group (based on the retail price per unit of the bulk pack) is highlighted with a grey background; in groups that contain biologics, the most cost-effective medicinal product is highlighted in lighter colour. These highlights are intended to visually support economical prescribing.

<u>Reimbursement outside of the EKO (inpatient market)</u>

This mainly concerns medicines that are administered in healthcare organisations, such as hospitals, or medicines that are directly administered by physicians in a medical practice. The reimbursement for such inpatient care is not subject to regulated (EKO) reimbursement procedures as laid out above. Rather, such drugs are publicly financed by a distinct hospital financial scheme, or the social security carriers will enter into private reimbursement agreements, either directly with the relevant physician, or this is agreed in the form of an overall contract between the relevant social security carrier and the competent medical association.

In many cases, hospitals purchase medicines directly from the manufacturer or marketing authorisation holder, with whom prices are negotiated – usually at the factory price or a lower retail

purchase price; this is typically done in the form of price negotiations or tendering procedure (public procurement) in case of public hospitals. Statutory wholesaler or pharmacy margins only apply in case the drugs are purchased directly from wholesalers or pharmacies.

The medicines to be purchased must appear on the hospital's internal medicine list, which is drawn up and updated by the hospital's medicines committee (which consists of members of the hospital pharmacy and hospital management, and often also of specialists and representatives of the social insurance). The promotion of drugs and interaction between pharmaceutical companies and healthcare organisations is subject to strict healthcare compliance and competition rules that *inter alia* limit the provision of benefits granted to healthcare organisations and healthcare professionals.

The necessary medical supplies required for the examination and treatment of patients, such as medicines, are usually provided free of charge by the social security carrier to the relevant physician or medical practice under the individual or overall healthcare contracts.

Pricing

General drug prices

Similar to most EU jurisdictions, the pricing of medicines is regulated by Austrian law. Outside the EKO procedure, the price basis for a medicine is the manufacturer's factory or depot price (*Fabrik- oder Depotabgabepreis*). The factory or depot price can be freely set by the company authorised to sell the medicine (Free Pricing Principle).

Wholesalers and pharmacist may add statutory mark-ups to the underlying prices (wholesale and pharmacy mark-ups) set forth by the Health Ministry (Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMSGPK)). A degressive margin system applies to Austrian pharmacies. This means that the pharmacy charges a higher percentage margin for products with a low purchase price and a lower margin for products with a higher purchase price; different pharmacy mark-up schemes apply for certain bodies (e.g. health insurance, with whom the pharmacies generate a major portion of total sales) and for private patients. As to wholesale margins, a maximum regressive mark-up scheme applies depending on whether a medicinal product is listed in the EKO (Green or Yellow area) or not.[39]

The respective mark-ups plus the applicable VAT for all medicinal products (currently at a reduced rate of 10%) are thus added to the factory or depot price.

While the price can be freely set, the Health Ministry must be notified of the price (*Preismeldung*).[40] Notwithstanding the above notification obligations, drug prices outside of the EKO are not subject to further pricing regulations or health technology assessments.

Pricing rules in the EKO procedure

Like in several other EU jurisdictions, such as France, Germany, Hungary or Norway, medicines listed in the EKO are subjected to drug price regulation by way of EPR. EPR systems generally comprise medicinal products that are grouped together with an identical active ingredient or in therapeutically similar groups. A fixed reimbursement amount, the reference price, is set for these medicines. The reference price usually corresponds to the medicine having the lowest price in the group.

For medicines listed in the EKO, the EU average price (referring to all other 26 EU Member States outside of Austria) is decisive – this price acts as a ceiling amount which must not be exceeded. The dossier submitted by the pharmaceutical entity (marketing authorisation holder or drug wholesaler) to the Pricing Committee (*Preiskommission*) at the Health Ministry must, amongst others, contain ex-factory price and wholesale price data of that medicine in the reference countries.

The Price Commission will determine the EU average price on the basis of prices in all EU Member States,[41] taking into account the statutory discounts granted in the respective Member States as well as list prices, for the purpose of setting the price of a medicinal product within the Red Box and Yellow Box.[42] The procedure for determining the EU average price are laid down in an ordinance setting forth complex pricing regulations.[43] The price must be determined within six months after the application of the pharmaceutical company on the basis of the dossiers submitted by the authorised distributors, and with the assistance of *Gesundheit Österreich GmbH* to review the price data.[44] Due to the fact that medicinal products are sometimes approved under different brand

names in EU Member States, the Price Commission will reference drugs with the same active ingredient, the same active-ingredient strength, dosage form and identical or almost the same pack size to calculate the EU average price.

A medicinal product is included in the Green Box if the relevant bodies recommend that, next to a similar therapeutic effect compared to existing EKO drugs in the Green Box, a sufficiently large price difference to the existing medicines can be agreed upon. Conversely, a higher price can only be agreed, provided that it is determined that the new drug has therapeutic added value compared to existing medicinal products in the Green Box.[45]

It is noteworthy that, as long as an EU average price has not been determined, the price reported by the pharmaceutical company is to be used provisionally. However, if the Price Commission finally determines that the provisional reimbursement price is higher than the determined EU average price, the pharmaceutical entity must repay the difference to the social insurance institutions within six months of a justified request.

The determined price acts as maximum amount and serves as a basis for the ensuing pricing negotiations. The final reimbursement price is usually subject to lengthy negotiations between the Dachverband (which usually must render a pricing decision within a statutory 180-day deadline) and the pharmaceutical company. If a price arrangement is reached, the underlying terms and conditions can be executed in a written contract. The reimbursement price stated in the EKO is then binding.

The pricing contract entered into is a civil contract; accordingly, the terms and conditions are usually subject to confidentiality and non-disclosure obligations. However, in the EKO, a distinct abbreviation "PM" (which stands for "price model")[46] is published, unless the marketing authorisation holder opposes the publication. Pricing agreements will typically set out the commercial and technical terms of pricing, procurement and invoicing such as rebates or price-volume agreements. Arrangements in the sense of managed-entry agreements (MEAs) are possible; MEAs can provide for cost and risk-sharing models, especially with regard to expensive drugs, to manage the uncertainty around the financial impact or performance of such products. MEAs can be based on drug prices (discounts and rebates, free medication, price-quantity agreements, budget caps) or on clinical results (performance-based payment: payment by result).

After the initial price determination, the Price Commission must again determine an EU average price after 18 months and after a further 24 months. In addition, the Price Commission may upon its discretion determine an EU average price after a further 18 months. The Price Commission must inform the Dachverband of the price determined in each case. The Health Ministry must publish the Price Commission's procedure for determining the price on the internet.

Price-links for generics and biosimilars

To maintain the financial integrity of the Austrian social security system, special pricing regulations are in place if a successor product with the same active ingredient for a generic or biosimilar is available. A price-link policy requires generic and biosimilar medicines to be priced below any originator or reference medicine that is included in the EKO at certain minimum percentages depending on whether the generic or biosimilar is the first, second or third product to be listed. The percentages for generics and biosimilars deviate by law:[47]

For generics: A (first) generic medicine will be included in the EKO if Dachverband agrees with the pharmaceutical entity on a price that is 28.6% lower than the reduced price of the original medicine. Additional generic products will be included if there is a sufficiently large price difference to the first generic product. This price difference exists in any case if:

- a price is agreed for the second generic product that is 18% lower than the price of the first generic product; and
- a price is agreed for the third generic product that is 15% lower than the price of the second generic product.

For biosimilars: A (first) biosimilar will be included in the EKO if Dachverband agrees with the pharmaceutical entity on a price that is 11.4% lower than the reduced price of the original medicine. Additional biosimilars will be included in the EKO if there is a sufficiently large price difference to the first biosimilar product. This price difference exists in any case if:

- a price is agreed for the second generic product that is 15% lower than the price of the first generic product; and

- a price is agreed for the third generic product that is 10% lower than the price of the second generic product.

Furthermore, there are consequences for the pricing of the originator or reference medicine; following entry of the generic/biosimilar product, the original medicinal product will only remain in the EKO if the relevant pharmaceutical entity, the market authorisation holder or authorised wholesaler, agrees to a price reduction of 30% within three months after the inclusion of the first generic or biosimilar.[48]

Additionally, prices must be reduced by law at certain stages. As soon as a third price reduction occurs through a successor product with the same active ingredient, the Dachverband must agree with the pharmaceutical entities of the original product and the successor products on an additional price reduction to the price of the third generic or the third biosimilar. If an agreement cannot be reached, the medicinal product must be deleted from the reimbursement code.

The Dachverband may, in certain cases, apply different pricing rules for selected indication groups in order to promote the availability of a successor product with the same active ingredient.

Marketing and promotion restrictions in the EKO

Any advertising intended for consumers is prohibited for EKO-listed medicines, including OTC drugs (medicines that do not require prescription).[49] However, this does not apply to OTC drugs that have been included in the EKO by the Dachverband on its own initiative against the will of the company entitled to distribute them.[50]

Policy issues that affect pricing and reimbursement

The procedural and policy aspects for inclusion in the EKO are laid down in the Austrian General Social Insurance Code (ASVG),[51] the Rules of Procedure Reimbursement Code (*Verfahrensordnung Erstattungskodex* – VO-EKO) and under general administrative procedures,[52] and essentially will consist of the following steps:

Application

The EKO application for inclusion of a drug is an administrative procedure and must be filed with Dachverband via an electronic form.[53] Dachverband provides a statutory form (*Formularsätze*) that must be used (German language requirement);[54] these include the initial application for inclusion, or additional applications for changes for use, packaging changes, price changes, deletion or inclusion.[55]

Examination and preliminary inclusion in the Red Box

Dachverband formally reviews the application for completeness and correctness,[56] and may request follow-up documents to be filed within 14 days. For inclusion in the EKO, the medicine must be approved (market authorisation) and must be available in Austria, and the application must include certain drug information (authorisation, active ingredient composition, package size, patent information, ATC classification, manufacturer, SoPC, samples, etc.), as well as information required for the MTA aspects, i.e. the required pharmacological, medical-therapeutic and health economic document lists.

If complete and correct, the medicine will be listed in the Red Box for a preliminary basis (Sec 20 VO-EKO). Upon doubt whether the medicine is reimbursable, Dachverband must issue a preliminary notice that the applicant must respond to within 14 days in writing,[57] and the Medicines Evaluation Committee (*Heilmittel-Evaluierungs-Kommission*) will issue a recommendation.

Inclusion in the Green or Yellow Box

Dachverband conducts an HTA and decides on the inclusion based on its price, additional therapeutic benefit for the patient and/or therapeutic innovation *vis-a-vis* medicinal products included in the EKO; additional documents can be requested from the applicant, to be provided within 14 to 30 days (Sec 21 VO-EKO)

Decision

Dachverband must decide in writing on the application for inclusion within 90 days; however, if the price is also decided, within 180 days of the application being submitted, based on the recommendation of the HEK. The deadline is suspended if the documents (e.g. studies, reports, etc.) are not submitted properly.

Legal Remedies

The decision (or the delay of a decision within the statutory deadline) by Dachverband can be challenged before the Federal Administrative Court (*Bundesverwaltungsgericht* - BVwG) within four weeks of being served.[58] The complaint must be filed at Dachverband via the Dachverband's internet portal; these remedies (with a few exceptions) have suspensive effect. The complaint fee is currently EUR 2,620 and must be borne by the losing party. Decisions by the Federal Administrative Court can be appealed at the Supreme Administrative Court (*Verwaltungsgerichtshof*) within six weeks, provided the case involves significant legal aspect to be resolved (for instance no body of case law on the relevant legal aspect); the appeal fee is currently EUR 240. Appeals require legal representation by an attorney at law.

Emerging trends

"Price range" limitations for the Green Box

Due to divergences in prices of medicines within the Green Box, a so-called price range limitation (*Preisband*) was established for the purpose of alignment in 2017, 2019 and 2021. As per this regulation, the price of the relevant medicinal products with the same active ingredient in the Green Box must not exceed the price of the cheapest medicinal product with the same active ingredient by more than 30% on the reference date (February 1 of the respective review year).[59] In return, deletion from EKO procedures for economic reasons for these drugs were not initiated.

In 2023, again, a new, adopted application was implemented, with a corridor of 20% to the cheapest drug speciality with the same active ingredient in the same or practically the same dosage form.

A renewed implementation of the price range in 2025 was decided with the 2023 ASVG amendment.[60]

These price range regulations were criticised by parts of the drug industry due to the increased pressure to lower the prices of EKO medicines. In particular, the Austrian Generics Association (OeGV) and the Austrian Biosimilars Association (BiVÖ), next to the price pressure that the price range exerts upon drugs, also see negative effects on supply of pharmaceuticals. [61]

Repayment obligations for drugs not listed in the EKO

For medicinal product that are not listed in the EKO reimbursement but that are still reimbursed in exceptional cases (at the expense of the Dachverband) a legal particularity exists:[62] if annual sales exceed EUR 750,000 for these medicines, the relevant pharmaceutical company must partially repay the amount to the social insurance. The Price Commission will determine the EU average price for these products as a benchmark. If the ex-factory price charged by social insurance exceeds the determined EU average price, a repayment obligation in excess of the difference arises for the relevant medicine.

New evaluation boards for drug pricing in hospitals

As from 2024, the federal healthcare organisation laws (KAKuG) set a process for the nationwide uniform, systematic evaluation of high-priced specialised medicinal products, the core of which is the establishment of an evaluation board.[63] This affects selected medicinal products that are to be used in hospitals or at the "interface" between the inpatient (hospital) sector and the outpatient sector.

The assessment board is to develop (non-binding) recommendations on the use of the assessed medicines based on HTAs and the prices negotiated with the pharmaceutical companies, and will subsequently publish them. Based on the EU HTA Regulation,[64] a clinical assessment (Joint Clinical Assessment) will already be available for certain drugs at an European level, and only supplementary assessments may take place at a national level.

The recommendations concern, in particular, the assessment of the additional medical-therapeutic benefit compared to the comparative therapy in conjunction with the economic efficiency, the use or non-use, certain application criteria or accompanying measures associated with the use (e.g. the establishment and filling of registers).[65]

Miscellaneous aspects: supply shortage measures

The drug supply on the Austria market is comparatively solid, still the proportion of medication packages that could not be delivered in May 2024 was 7.5%.[66] Delivery bottlenecks result from various factors, such as parallel imports, which affect the Austrian market due low price level compared to the rest of the EU – special laws are in place that allow for a ban of parallel imports where necessary .[67]

In order to cope with peaks in demand due to acute shortages in winter 2023/2024, the Ministry of Health and the pharmaceutical wholesalers' association (PHAGO) have set up a drug warehouse. This warehouse contains all the necessary active ingredients for common antibiotics and medicines for cold symptoms. Upon high demand, pharmacies can call on these active ingredients and ensure that the population is supplied with magistral prepared medicines. The fee for the magistral preparation of medicines by pharmacies has now been increased by an average of 50%.

Further, amongst other measures, the pharmaceutical industry is now required to store larger quantities of critical medicines, thereby significantly increasing its existing stocks of critical medicines. Around 700 relevant medicines are to be stored in the future to meet Austria's four-month needs. These include, in particular: painkillers; antibiotics; medicines for cold symptoms; and also preparations for chronic cardiovascular or lung diseases.

Structural reforms and prescriptions

Due to high costs in the hospital area, Austria provides, amongst other measures, structural incentives to the healthcare sector so that patients can be treated according to the motto "digital before outpatient before inpatient". In hospitals, specialist outpatient clinics, day clinics and upstream facilities will be expanded so that fewer patients have to be admitted as inpatients.

Moreover, the scope of healthcare professionals allowed to prescribe drugs has expanded. In the future, qualified nursing staff will be permitted to prescribe selected medicines for the first time (to date, only physicians are allowed to do so). The exact list of medicines will be determined by way of ordinance of the Health Ministry.

Successful market access

Market access in Austria requires prior technical, regulatory and legal assessments of the medicinal product and the suitable distribution model, ideally by seeking assistance by local council and regulatory advisors. Depending on the selected distribution model, a legal entity or branch office will have to be established and registered in Austria, requiring the relevant trade licences and drug wholesale distribution licences from the competent authorities; alternatively, a local authorised distributor model can be employed.

The Austrian healthcare system for drug pricing and reimbursement essentially distinguishes between the outpatient sector, which is subject to price regulations and reimbursement by social security carriers, and the unregulated inpatient sector, which (depending on whether a public entity is involved) is subject to free price negotiations or tender procedures. In the supply chain, prices of all medicines are regulated through regressive mark-up schemes for wholesale and pharmacies.

If pricing and reimbursement in the outpatient sector (thus a registration in the EKO) is sought, special due diligence and preparation with regard to submission documentation for the health technology evaluations and the pricing negotiations are advisable. For high-priced drugs, the stakeholders – such as the responsible social security carriers in the outpatient sector, or hospitals in the inpatient sector – may negotiate MEAs setting out confidential pricing terms, such as discounts and rebate schemes. Further, before the application, discussions and meetings with authorities/stakeholders are possible.

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Dr. Daniel Larcher is an attorney at law practising in Vienna, Austria. He was admitted to the bar in 2010. He specialises in commercial law and public commercial law, focusing on healthcare, contracts and distribution.
Daniel has many years of experience in advising and representing private and public companies, as well as agencies and industry associations on a national and international level. His law firm, LarcherLaw (https://www.larcherlaw.at), focuses on all legal aspects concerning the field of Life Sciences & Healthcare, especially the medical product industries such as pharma (medicinal products) and medical devices/IVDs with regard to market access, product authorisations or interactions with stakeholders. This includes pricing and reimbursement matters, in particular legal and regulatory advice, contract negotiations and representation before authorities and courts.
Daniel is the author of numerous publications in his areas of specialisation and gives lectures, workshops and training courses.

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Mag.ª pharm. Claudia Reisinger works as a pharmacist in Vienna. She has obtained a Mag.ª pharm. degree from the University of Vienna. She completed her studies in pharmacy in 2014 with distinction. She wrote her diploma thesis at the Department of Pharmacology with the title "*Investigation of the stress-reducing effect of a subtype-selective $GABA_A$ receptor modulator and derivatives*" (*Untersuchung der Stress-reduzierenden Wirkung eines Subtyp-selektiven $GABA_A$ Rezeptor Modulators und Derivate*, 2014)). During her studies, she received merit scholarships from the University of Vienna and gained experience in various public pharmacies and in a hospital pharmacy. She then completed the one-year aspirant training in a pharmacy in Vienna. Claudia has completed numerous training courses, including courses on medication management and the vaccination training of the Chamber of Pharmacists. In addition to professional advice, her main tasks include the manufacture of magistral medicines, the dispensing and manufacture of narcotic drugs and the management of the narcotic drug book.

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Endnotes

[1] https://www.statistik.at/statistiken/bevoelkerung-und-soziales/bevoelkerung/bevoelkerungsstand/bevoelkerung-zu-jahres-/-quartalsanfang

[2] https://www.statistik.at/statistiken/bevoelkerung-und-soziales/bevoelkerung/demographische-prognosen/bevoelkerungsprognosen-fuer-oesterreich-und-die-bundeslaender

[3] https://www.pharmig.at/media/6555/2024-pharmig_daten-fakten_de.pdf

[4] https://www.pharmig.at/media/6555/2024-pharmig_daten-fakten_de.pdf.

[5] https://www.statistik.at/statistiken/bevoelkerung-und-soziales/gesundheit/gesundheitsversorgung-und-ausgaben/gesundheitsausgaben

[6] https://www.statistik.at/fileadmin/announcement/2024/06/20240612Gesundheitsausgaben2023.pdf

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[13] https://www.pharmig.at/media/6555/2024-pharmig_daten-fakten_de.pdf

[14] Sec 133 Austrian General Social Insurance Code (*Allgemeines Sozialversicherungsgesetz* – ASVG).

[15] Sec 136 para 1 item a ASVG.

[16] 10 ObS 118/12v; RIS-Justiz RS0083921.

[17] See Art 1 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; Sec 1 Austrian Pharmaceutical Act (*Arzneimittelgesetz* – AMG).

[18] List of goods published by the Austrian Chamber of Pharmacists as of 1 January 2023 (*Warenverzeichnis des Österreichischen Apothekerverlags* 1 January 2023).

[19] https://www.ris.bka.gv.at/Avsv

[20] Sec 30b para 1 Item 4 ASVG.

[21] Sec 133 para 2 ASVG.

[22] Sec 30b para 1 item 4c ASVG.

[23] ECJ 17.07.2008 C-311/07.

[24] Sec 351c para 2 ASVG; Sec 8 Guidelines on the economical prescription of medicinal products and medical devices (*Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen* – RöV).

[25] Sec 351c para 2 ASVG.

[26] List of non-reimbursable drug categories as per §351c Abs2 ASVG (*Liste nicht erstattungsfähiger Arzneimittelkategorien nach* §351c Abs2 ASVG).

[27] Sec 31 para 3 item 12 ASVG, Sec 8 RöV.

[28] Sec 20 para 4 Rules of Procedure Reimbursement Code (*Verfahrensordnung Erstattungskodex* – VO-EKO).

[29] Sec 31 para 3 item 12 ASVG, Sec 6 para 1 item 2 RöV.

[30] Sec 30b para 1 item 4d ASVG.

[31] Especially regarding Green Box listings, Sec 351c Para 8 ASVG.

[32] Especially for the Yellow Box, Sec 351c Para 8 ASVG.

[33] Sec 351c Para 3 ASVG.

[34] Sec 23 VO-EKO.

[35] Sec 23 para 2 VO-EKO.

[36] Sec 24 *et seq.* VO-EKO.

[37] Sec 25 VO-EKO.

[38] Sec 25 para 2 to 6 VO-EKO.

[39] https://www.sozialministerium.at/Themen/Gesundheit/Medizin-und-Gesundheitsberufe/Medizin/Arzneimittel/Arzneimittelpreise.html

[40] Forms available at: https://www.sozialministerium.at/Themen/Gesundheit/Medizin-und-Gesundheitsberufe/Medizin/Arzneimittel/Arzneimittelpreise.html

[41] Sec 9 para 3 Price Act (*Preisgesetz* 1992).

[42] https://www.sozialministerium.at/Themen/Gesundheit/Medizin-und-Gesundheitsberufe/Medizin/Arzneimittel/Arzneimittelpreise/EU-Durchschnittspreise-laut-ASVG.html

[43] Ordiance on the procedure of the Price Commission for the determination of the EU average price as per Sec 351c para 6 and para 9a ASVG (*Regelung für die Vorgehensweise der Preiskommission für die Ermittlung des EU-Durchschnittspreises gemäß* § 351c Abs. 6 and Abs. 9a ASVG*)* – Price Ordinance*;* EU-Durchschnittspreise laut ASVG (sozialministerium.at).

[44] Sec 4 Price Ordinance.

[45] Sec 351 para 9 ASVG.

[46] Defined as: "Medicinal products for which an agreement on a pricing model has been concluded with the company authorised to distribute them." ("*Arzneispezialitäten, für die eine Vereinbarung über ein Preismodell mit dem vertriebsberechtigten Unternehmen vorliegt.*")

[47] Sec 351c para 10 ASVG.

[48] Sec 351c para 10 ASVG, Sec 25 para 2 item 1b VO-EKO.

[49] Sec 351g para 5 ASVG.

[50] Sec 351c para. 5 ASVG.

[51] Secs 351c *et seqq*.

[52] *Allgemeines Verwaltungsverfahrensgesetz* 1991 – AVG.

[53] Sec 11 para 1 VO-EKO.

[54] Sec 12 VO-EKO.

[55] https://www.sozialversicherung.at/cdscontent/?contentid=10007.821533&portal=svportal

[56] Sec 21 VO-EKO.

[57] Sec 20 para 3 VO-EKO.

[58] Sec 351h ASVG.

[59] Sec 351c para 11 ASVG.

[60] Art 5 BGBl. I No. 200/2023.

[61] https://www.generikaverband.at/inhalts-hub/arzneimittelversorgung-ist-weiterhin-gefahrdet

[62] BGBL. 32/2022, Sec 351c para 9a ASVG.

[63] Sec 62 *et seqq.* Federal Act on Hospitals and Health Resorts (*Krankenanstalten- und Kuranstaltengesetz* – KAKuG).

[64] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU.

[65] Sec 62e para 4 KAKuG.

[66] https://www.sozialversicherung.at/cdscontent/?contentid=10007.898799&portal=svportal

[67] Ordinance of the Federal Minister for Social Affairs, Health, Long-Term Care Consumer Protection on Ensuring the Supply of Medicines. (*Verordnung des Bundesministers für Soziales, Gesundheit, Pflege und Konsumentenschutz über die Sicherstellung der Arzneimittelversorgung*.).