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Pharmaceutical regulation and policies in Austria

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Abstract

Austria is a middle-sized, high-income country in Central Europe with universal health coverage and a highly fragmented health care system. Medicines for outpatient use that are reimbursed by the social health insurance are price-regulated, whereas medicines for inpatient use are neither subject to price regulation nor to health technology assessment (HTA). These medicines are procured by hospitals, hospital groups and provinces which are the main owner of public hospitals. The major pricing policy for new medicines in the outpatient sector is external price referencing. Austria refers to all other 26 European Union (EU) Member States; the determined benchmark price must not exceed the EU average price. External price referencing is based on list prices, but the statutory manufacturer discounts applicable in some reference countries are considered. Regular price reviews with subsequent price adjustments are in place. For generic and biosimilar medicines to be included in the outpatient positive list, a price link policy is applied with different reduction rates for generics and biosimilars. In the supply chain, prices of all medicines are regulated through regressive mark-up schemes for wholesale and community pharmacies. The inclusion in the outpatient positive list is based on an HTA process which comprises pharmacological, medical-therapeutic and economic evaluations, followed by price negotiations about the reimbursement price. For medicines with high financial burden for the public payers, the Austrian Social Insurance (for the outpatient sector) and procurers for hospitals tend to conclude managed-entry agreements with confidential discounts. For outpatient medicines, patients are charged a fixed prescription fee per prescribed item; no further co-payments apply for outpatient or inpatient medicines. Studies have shown that the current pricing and reimbursement policies in Austria have contributed to keep prices of outpatient medicines stable (high-cost medicines tend to range above EU average), whereas the unregulated prices of medicines used in hospitals are frequently the highest in European comparison. Pharmacy mark-ups are also high in comparison to other European countries.

Keywords: pharmaceutical preparations; Austria; Europe; pricing; reimbursement; coverage; health technology assessment; legislation.

Regulação e políticas farmacêuticas na Áustria

Resumo

A Áustria é um país da Europa Central, de médio porte e renda alta, com cobertura universal de saúde e um sistema sanitário altamente fragmentado. Os medicamentos para uso ambulatorial cobertos pelo seguro social de saúde têm preços regulados, enquanto medicamentos para uso hospitalar não são sujeitos à regulação de preços ou à avaliação de tecnologias de saúde (ATS). Esses últimos são adquiridos por hospitais, grupos de hospitais e províncias os quais são os principais proprietários dos hospitais públicos. A principal política de preços para novos medicamentos no setor ambulatorial é a precificação por referenciamento externo de preços. A Áustria usa como referência todos os outros 26 Estados-Membros da União Europeia (UE) e o preço de referência determinado não deve exceder o preço médio da UE. O referenciamento externo é baseado em preços de lista, onde são considerados os descontos legais do fabricante, aplicáveis em alguns países de referência. Estão em vigor revisões regulares e subsequentes ajustes de preços. Para medicamentos genéricos e biossimilares a serem incluídos na lista positiva ambulatorial, é aplicada uma política de vínculo de preços com diferentes taxas de redução. Na cadeia de abastecimento, os preços de todos os medicamentos são regulados por meio de esquemas de margem regressiva para distribuidores e farmácias comunitárias. A inclusão na lista positiva ambulatorial é baseada em um processo de ATS, que compreende avaliações farmacológicas, médico-terapêuticas e econômicas, seguidas de negociação de preços de reembolso. Para medicamentos com elevada carga financeira para os pagadores públicos, o Seguro Social austríaco, responsável pelo setor ambulatorial, e os compradores hospitalares, tendem a celebrar contratos de entrada gerenciada (managed-entry agreements), com descontos confidenciais. É cobrada dos pacientes uma taxa fixa por item ambulatorial prescrito, mas nenhum outro copagamento é aplicável. As atuais políticas de preços e reembolso na Áustria contribuíram para manter os valores dos medicamentos ambulatoriais estáveis enquanto os preços não regulamentados dos de uso hospitalar são frequentemente os mais altos na comparação europeia. Já os medicamentos de alto custo tendem a variar acima da média da EU. As margens das farmácias também são altas em comparação com outros países europeus.

Palavras-chave: preparações farmacêuticas; Áustria; Europa; preços; reembolso; cobertura; avaliação de tecnologia em saúde; legislação.

Austria and its health system

Austria is a middle-sized country (83,879 km²)[1] in Central Europe. It has a population of 8.93 million (as of 1 January 2021),[2] which corresponds to a rather low density (106 inhabitants per km²) due to some mountainous, scarcely populated regions.

With its gross domestic product (GDP) per capita of 55,408 United States dollars Purchasing Power Parities (USD PPP, in current prices; total GDP of 470 billion USD PPP) in 2020,[3] Austria is considered a high-income country according to the World Bank Classification. Similar to other European countries, Austria has been experiencing a decline in economic growth because the COVID-19 pandemic has resulted in a health crisis as well as economic crisis.[4]

Austria is a parliamentary republic that has nine provinces, with the capital city of Vienna being both a municipality and a province. Decision-making powers are shared between the federal state and the provinces. In health care the provinces have considerable powers, as, for instance, they own most of the hospitals. At federal level, the major institutions are the Federal Ministry of Social Affairs, Health, Care and Consumer Protection and the Austrian Social Insurance.[5] Austria has been a member of the European Union (EU) since 1995, and it has the EU's common currency, the euro. As a 'Schengen country', it is one of 26 European countries that abolished their internal borders for the free movement of its people.[6]

Life expectancy at birth has increased over the last decades and amounts to 81.8 years on average (women: 84.1 years, men: 79.4 years, data for 2018), which is slightly above the EU average. Similar to other European countries, cardiovascular diseases (e.g. strokes and myocardial infarctions) and cancer are the main causes of mortality (around two thirds of all deaths) in Austria.[4]

As of April 2021 (the date to which the description in the case study refers to), the Austrian health care system is based on a social health insurance (SHI) model, and the health system is financed by a mix of compulsory SHI contributions and general tax revenues. 99.9% of the population is covered by statutory SHI, while supplementary voluntary health insurance only plays a minor role.[7] With the implementation of the major social insurance reform, the number of sickness funds was reduced from 21 to five in 2020.[8] It is mandatory for insured people to be a member of a sickness fund (in accordance with their regional employment affiliation and vocational group), and there is no free choice of the sickness fund. In principle, all sickness funds offer the same level of services, but co-payments may vary. In EU comparison Austria has the second highest per capita health expenditure after Germany, and pharmaceutical expenditure per capita is also above EU average [data adjusted by purchasing power parities (PPP), 2019]. In terms of public funding, the shares in health and pharmaceutical spending are above EU average, Table 1.[4]

In the outpatient sector, health care is provided by general practitioners and specialists, including those in a contractual relationship with one or more sickness funds (so-called 'contract doctors'). They are remunerated by contact capitation (a fixed fee per enrolled patient per quarter) and fees-for-service. In the outpatient specialist sector, non-contracted providers account for an important share, particularly in urban areas. Patients pay for 'private physicians' (i.e. those that do not have a contract with one or more sickness funds), and subsequently they can ask for reimbursement of 80% of the applicable SHI tariff. Doctors are allowed to work both in a hospital (as an employee of a usually publicly owned hospital) and have their own practice.

In addition to the above-mentioned social health insurance reform implemented in 2020, the Austrian health care system has been subject to a long-term reform process entitled 'Target-Based Governance' for more than a decade. It provided for numerous projects in several areas of health care, including the pharmaceutical sector. A major reform concerns the implementation of an annual capping of the publicly funded health expenditure as well as the introduction of primary health care centres. In the pharmaceutical sector, the second Federal Target-Based Governance Agreement running from 2017 until 2021 (following the first one of 2013 until 2016) includes plans for optimising pharmaceutical provision through better coordination in procurement across outpatient and hospital sectors, the establishment of a 'Clearing House' for the anonymous exchange of 'net prices' and volume data between public procurers, the introduction of prescribing by International Non-Proprietary Name (INN) and improvements in Health Technology Assessment (HTA).[9] These projects are, however, on hold or have not yet been concluded.

Pharmaceutical market

In 2017, pharmaceutical production in Austria amounted to 2,712 million euro, corresponding to 309 euro per inhabitant. In per capita, Austrian pharmaceutical production was slightly lower than in France, Spain and UK, whereas the highest per capita production value was reported from Switzerland (5,338 euro) and Ireland (4,035 euro).[10] Austria is an export country of pharmaceutical products, with a positive trade balance (+ 3.6% in 2017).[10]

In 2019, the Austrian pharmaceutical market reported sales worth 4,583 million euro (thereof 1,504 million euro in the hospital sector and 3,079 million euro in the outpatient sector). In terms of volume, 233 million packs were sold in Austria, thereof 20.4 million packs to hospitals (around 9%) and 212.7 million packs (around 91%) to community pharmacies. Compared to the previous year, the pharmaceutical market grew in value (+4.3%) and decreased in volume (-0.5%); this diverging trend pointing to high medicine prices was particularly observed in the hospital sector (+8.2% in value,-3.0% in volume).[10]

Latest available comparable data for Organisation for Economic Development and Cooperation (OECD) countries (year 2017 or nearest year) show generic market shares of 52% in volume on OECD average (total pharmaceutical market or reimbursement market), with some countries (e.g. Germany, UK) of more than 70% and 80% in volume.[11] Austria has a generic market share of 55% in volume[11] which appears to be rather high at first glance, but Austrian data relate to

Table 1. Health and pharmaceutical expenditure in Austria in European Union comparison.

Expenditure data 2019[1] (adjusted by purchasing power parity / PPP)	**Health expenditure**		**Pharmaceutical expenditure**[2]	
	Austria	**EU-27**	**Austria**	**EU-27**
Expenditure per capita (USD PPP)	3,966	2,572	463	381
Share of GDP or HE[3] (%)	10.4	8.3	17 (2018)	21 (2018)
Share of public expenditure (%)	75 (2018)	73 (2018)	69 (2018)	58 (2018)

[1] Data refer to 2019 unless indicated differently; averages are provided for EU-27 (excl. UK). [2] Only retail pharmaceutical expenditure (outpatient sector). [3] Health expenditure: share in % of gross domestic product (GDP); pharmaceutical expenditure: share in % of health expenditure (HE).
Source: OECD / European Commission[4]

the generic share in the outpatient off-patent reimbursement market (i.e. the specific market segment in which generics and biosimilars are available). Generic penetration has still an important potential to be increased, however there is a lack of demand-side measures to enhance the uptake of off-patent medicines.

Pharmaceutical regulation

In the EU, marketing authorisation has been harmonized (for details of the marketing authorisation processes in an EU country see Additional Information 1).[12] The regulator in Austria is the Federal Office for Safety in Health Care [*Bundesamt für Sicherheit im Gesundheitswesen* (BASG)] which is responsible for marketing authorisation and the vigilance of human and veterinary medicines. The BASG sub-division AGES Medizinmarktaufsicht AGES [Austrian Medicines and Medical Devices Agency (*Medizinmarktaufsicht*)] takes care of the pharmaceutical agenda and thus acts as the medicines agency.

Overview of pricing and reimbursement of medicines

In Austria, medicines that are included in the outpatient reimbursement list [the so-called Reimbursement Code, *Erstattungskodex* (EKO)] are subject to price regulation. Medicines procured for inpatient use and non-funded medicines are not price-regulated. In 2017, the scope of price regulation was extended to medicines not included in the Reimbursement Code in case that their sales at the expense of social health insurance exceed an annual threshold of 750,000 euro (at ex-factory price level). The new regulation concerns medicines that were marketed following procurement by hospitals (thus, no price regulation and no HTA) but they cause costs for the social health insurance when they are prescribed in the outpatient sector.[5]

The pricing and reimbursement decision takes place after a medicine has been granted marketing authorisation and upon applications of the marketing authorisation holder (MAH) to the competent authorities: The latter include the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection [*Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz* (BMSGPK)] which decides on the price of medicines and the Austrian Social Insurance (*Dachverband der Sozialversicherungsträger*) which is in charge of reimbursement decisions for outpatient medicines. In taking a pricing decision, the Ministry of Social Affairs, Health, Care and Consumer Protection is supported by the Pricing Committee (***Preiskommission***) that comprises several stakeholders (other Federal Ministries and the 'social partners' such as the Federal Chamber of Commerce and the Federal Chamber of Labour). Key legislation is the General Social Insurance Law [*Allgemeines Sozialversicherungsgesetz* (ASVG)][13] and the Price Act (*Preisgesetz*).[14]

Figure 1. HTA process for the inclusion of medicines into reimbursement in the outpatient sector.

First step: Pharmacological evaluation
Aim: To determine comparable medicines (incl. their dosage), based on the ATC-4 code level To determine the added therapeutic benefit in comparison to alternatives (e.g. other medicines, other forms of treatment)
The **degree of innovation** is determined on an eight-scale range. 1. Same active ingredient, same strength and practically same pharmaceutical form as listed medicine(s) 2. Same active ingredient and practically same pharmaceutical form but new strength 3. New combination of active ingredients already listed 4. New pharmaceutical form of already listed active ingredient(s) 5. New active ingredient belonging to a listed therapeutic group of uniform treatment principle 6. New active ingredient with a new treatment principle for treating a disease with listed treatments 7. New active ingredient providing first treatment with a medicine for a disease previously treated otherwise 8. First treatment of a disease

↓

Second step: Medical-therapeutic evaluation
Aim: To determine and quantify to the group of patients to be treated To determine and quantify the therapeutic benefit of the medicine in comparison to therapeutic alternatives To determine the validity of the information of the submitted pharmacoeconomic studies
The **degree of the therapeutic benefit** is determined on a six-scale range: 1. No added therapeutic value 2. Further therapeutic option of similar benefit as medicine listed 3. Added therapeutic benefit for a subgroup of patients 4. Added therapeutic benefit for the majority of patients 5. Substantial therapeutic benefit for a subgroup of patients 6. Substantial therapeutic benefit for the majority of patients

↓

Third step: Economic evaluation
Aim: To assess whether, or not, the expected cost/benefit ratio is justified in the context of available therapeutic alternatives listed in the Reimbursement Code.
The **price** is determined based on the six scale of therapeutic benefit assessment: If no added therapeutic value → according to price link rules If further therapeutic option of similar benefit as medicine listed → at least 10% lower than the comparator listed If added therapeutic benefit for a subgroup of patients → maximum 5% higher than the comparator listed If added therapeutic benefit for the majority of patients → maximum 10% higher than the comparator listed If substantial therapeutic benefit for a subgroup of patients → higher price based on a mandatory pharmacoeconomic study If substantial therapeutic benefit for the majority of patients → higher price based on a mandatory pharmacoeconomic study

ATC = Anatomical Therapeutic Chemical classification system. Source: Procedural Rules for publication of the Reimbursement Code[16]

Pricing

The major pricing policy for new medicines is external price referencing (EPR). Austria refers to all other 26 EU Member States (UK was excluded from the country basket after Brexit). The dossier submitted by the MAH to the Pricing Committee has to contain ex-factory price and wholesale price data of that medicine in the reference countries. In line with the ASVG law,[13] the Pricing Committee can ask the Austrian National Public Health Institute [*Gesundheit Österreich GmbH* (GÖG)]. to review the price data. Based on the price information for the other countries, the Pricing Committee determines the so-called 'European average price' which must not exceed the EU average price. Considered prices are list prices, and official statutory manufacturer discounts are taken into account. For countries where neither ex-factory prices nor wholesale margins are regulated, average wholesale margins are assumed, as published in the procedural rules.[15] If proven by the invoices provided by the MAH that the actual margin differs from the assumed average wholesale margin, the actual wholesale margin is used for the calculation of the benchmark price instead of the assumed average margin. GÖG is tasked to annually review the information on statutory manufacturer discounts and average wholesale margins in the reference countries, and the findings are published.[15]

The determined price is a maximum price, and it serves as a basis for the reimbursement price. The latter is achieved through negotiations between the Austrian Social Insurance and the MAH, which may, or may not, result in the conclusion of a managed-entry agreement (MEA). The decision on the inclusion into reimbursement, and the reimbursement process is – as described in further detail below – informed by an HTA based on pharmacological, medical-therapeutic and economic evaluations in which the added therapeutic benefit is a major criterion for granting higher prices (value-based pricing components).[16]

Due to the provisions of the EU Transparency Directive[17], the decision-making process on pricing and reimbursement must be concluded within 180 days. Thus, a price is determined within six months upon receipt of a company's price application. Price evaluations undertaken by the Pricing Committee are mandatory 18 months after the first time a price was set and 24 months after the second time a price was set. Another re-evaluation is possible 18 months after the third time a price was determined. The Austrian Social Insurance may also review the reimbursement status and the reimbursement price of a funded medicine but there are no defined deadlines.

EPR is applied ex-post for medicines which are not included in the Reimbursement Code but whose sales at the expense of the Austrian Social Health Insurance exceed 750,000 euro (at ex-factory price basis) during the last twelve months. If the 'European average price' determined by the Pricing Committee is lower than the price that had been set by the MAH, the pharmaceutical company has to repay the difference from the point in time when the turnover threshold was first exceeded.[13]

Internal price referencing is applied for off-patent medicines in the outpatient sector if the MAH aims to have them included in the Reimbursement Code. A price link policy is in place: as a prerequisite for the inclusion into outpatient reimbursement, the generic and biosimilar medicines are priced at a certain percentage lower than the originator or reference medicine already listed in the Reimbursement Code. Since a 2017 SHI reform, the percentage rates for generics and biosimilars differ: the first generic is priced at least 50% below the price of the originator medicine which went off-patent, whereas this rate amounts to 38% for biosimilars. The second and the third generics are required to have a price difference of 18% and 15%, respectively, in relation to the previously included generics (for biosimilars the rates are 15% and 10%, respectively). Further generics and biosimilars have to offer a price reduction of at least € 0.10 compared to the previous ones. The Austrian internal price referencing system requires that the price of the originator and the reference medicine decreases by at least 30% within three months after the inclusion of the first generic or first biosimilar medicine into the Reimbursement Code. There is no reference price system in place in which substitutable medicines are clustered and attributed the same reimbursement price.[18]

For all other medicines, there is, in principle, free pricing. Pharmaceutical companies have to notify the Ministry of Social Affairs, Health, Care and Consumer Protection about the ex-factory price for new medicines and about price changes. If a notified price is considered to be too high in the context of the Austrian economy, the Ministry can officially start a price setting procedure. If such a procedure has not been started within six weeks, the proposed price is considered to be accepted.[14]

There are no specific pricing criteria for special situations such as shortages or public health emergencies. Cost-plus pricing is not applied.[5]

In the supply chain, all medicines used in the outpatient sector are subject to statutory regressive schemes of maximum mark-ups. There are different wholesale mark-ups for different types of reimbursable medicines, and for community pharmacies the mark-up rates in the scheme for 'privileged customers', such as the sickness funds, the State, the provinces, municipalities, funds and institutions held by these, as well as non-profit hospitals, are lower than those of the mark-up scheme applied for private customers. The value-added tax on medicines is 10% compared to the 20% standard rate in Austria.[5]

The reimbursement prices of outpatient medicines included in the Reimbursement Code are published.[19] Recent decisions on the maximum list prices are publicly accessible at the Ministry's website.[20] But a complete picture of the price data for nearly all medicines marketed in Austria (prices of some hospital medicines are missing) is only provided in a database offered by a publishing house of the Pharmacy Chamber. This database is accessible against a subscription fee.[21]

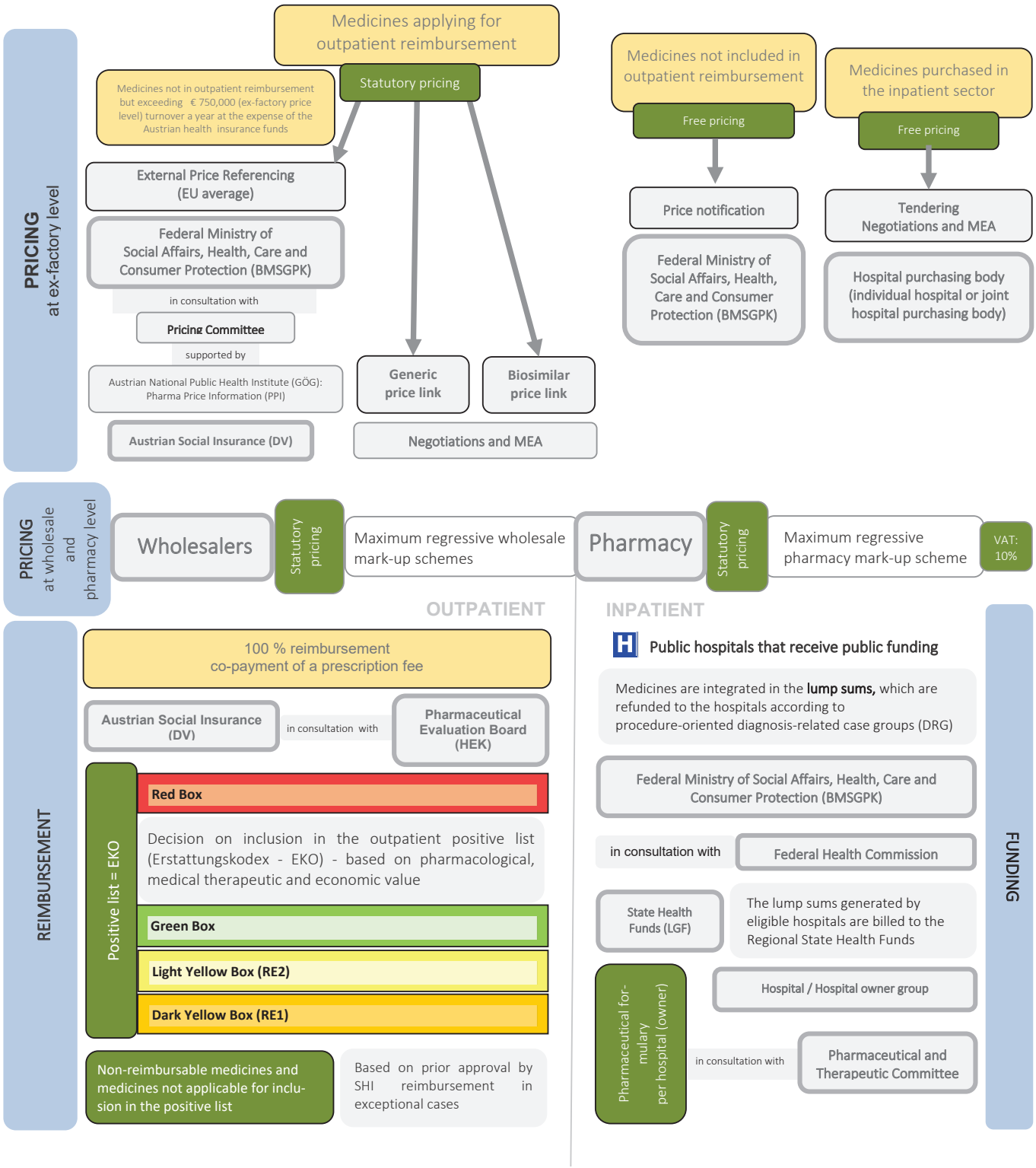
Health Technology Assessment and reimbursement

To be granted public funding for a medicine used in the outpatient sector, the MAH must submit a request for inclusion of the medicine into the Reimbursement Code. Apart from some defined categories of medicines (e.g. contraceptives), all medicines which have an active marketing authorisation and can be supplied are eligible for reimbursement.[5]

The request for reimbursement has to be accompanied by a dossier which allows the Austrian Social Insurance to carry out an HTA. The submission must include the Summary of Product Characteristics (SPC), the European Public Assessment Report (EPAR), the information of the prices in the other EU Member States and maximum three clinical studies that are considered to be of key importance. The MAH is also asked to provide an assessment of the degree of innovation and of the therapeutic benefit of the medicine.[16]

The HTA involves three steps: a pharmacological evaluation, a medical-therapeutic evaluation and a health-economic evaluation, which follow one after the other, Figure 2. The Procedural Rules for publication of the Reimbursement Code[16] describe the principles of the evaluations. The evaluations should be based on published data that are accessible in peer-reviewed articles in scientific journals and assessments of independent institutions and authorities. Further information (e.g. expert statements, unpublished studies) require a conflict of interest statement of the authors and are lower ranked regarding the validity of evidence.[16]

Figure 2. Workflow of a pricing and reimbursement decision in Austria, 2021.



EKO: *Erstattungskodex* (Reimbursement Code); DRG: diagnosis-related groups; MEA: managed entry agreement; SHI: social health insurance; EU: European Union; VAT: Value Added Tax

The therapeutic value of a medicine is evaluated in the indication for which it was authorised, and in comparison to available alternatives. If a new medicine demonstrates a higher therapeutic benefit for patients compared to existing medicines already listed in the Reimbursement Code, it is granted a higher price. If the therapeutic benefit is equal, the new medicine is given a lower price compared to the price of the already listed medicines, and in case of lower comparable therapeutic benefit, it is not included in the Reimbursement Code. Additionally, there is the threshold of the 'European average price' since the price of a medicine to be included in the Reimbursement Code must not exceed the average of the prices in the other EU Member States.[5]

Based on the outcome of these three evaluations conducted by staff of the Austrian Social Insurance, the Medicines Evaluation Committee [*Heilmittelevaluierungskommission* (HEK)] makes a recommendation. The Medicines Evaluation Committee is an Advisory Board that comprises 21 members from the different institutions (representatives of the social insurance system, the Chamber of Commerce, the Chamber of Labour, the Chamber of Doctors, the Chamber of Pharmacists, independent scientists and – without voting rights – of the provinces). Based on the recommendations of the Medicines Evaluation Committee, which meets monthly, the Austrian Social Insurance takes the decision on the inclusion of a medicine at a determined reimbursement price into the Reimbursement Code.[5]

This decision by the Austrian Social Health Insurance is taken as part of a negotiation with the MAH. In case of medicines that pose high financial burden, a managed-entry agreement (MEA) is concluded. Its content is confidential, but the Austrian Social Insurance flags the medicines under a MEA in the Reimbursement Code unless the MAH opposes the publication of this labelling.[5]

The decision of the Austrian Social Insurance on the reimbursement state and a reimbursement price is applicable for the whole country. The funding for reimbursable medicines is provided by the sickness funds. If a MAH does not agree with the decision of the Austrian Social Insurance, an appeal can be submitted to the Federal Administrative Court (*Bundesverwaltungsgericht*) within 180 days.[5]

When included in the Reimbursement Code, medicines are attributed to a specific category ('box'): The 'green box' includes medicines that qualify for automatic reimbursement; these medicines may be prescribed by any 'contract doctor' of a sickness fund. The 'yellow box' includes medicines which demonstrate a substantial added therapeutic benefit. The 'yellow box' is divided into a 'dark yellow' box, whose prescription requires the ex-ante approval of a 'chief physician' of a sickness fund, and a 'light yellow box', for which ex-post control of the records kept by the prescribing doctor might be applied instead.[5, 16]

During a period of maximum six months between the submission of the request for reimbursement and the decision, the medicine is temporarily included in the Reimbursement Code in the so-called 'red box'. The prescription of medicines in the 'red box' also requires the ex-ante approval of a doctor at a sickness fund.[5, 16]

In the hospital sector, medicines are integrated into lump sums, which are funded to the hospitals according to diagnosis-related groups (DRG). Solely some oncology medicines are defined as single medical procedures [*Medizinische Einzelleistungen* (MEL)], and their utilisation is individually reimbursed.[5]

There is no national positive list of medicines used in hospitals but the hospitals (or hospital groups of the same hospital owner such as a province) have their own hospital pharmaceutical formulary (HPF): Only medicines which are included in the HPF are procured. Procurement is done at the level of the hospitals, or of groups of hospitals. Since public hospitals are mainly owned by the Austrian provinces, some provinces procure several medicines for the hospitals they own. For high-cost medicines, MEA have been concluded.[5]

No systematic HTA process is in place for the procurement of medicines in the hospital sector. A pilot project (so-called '*Spitals-HEK*', to be translated as 'Hospital Pharmaceutical Evaluation Board') was launched to explore the possibility of HTA in the case of three medicines.[5]

AIHTA, the Austrian Institute for Health Technology Assessment, performs horizon scanning for oncology medicines to provide evidence for decision-makers. More than 130 reports, including updates, have been provided since its launch in 2009.[22] In 2020, AIHTA also started to do horizon scanning on COVID-19 medication.[23]

Medicines included in the outpatient Reimbursement Code and used in hospitals are fully funded. For filling a prescription in a community pharmacy, patients are charged a prescription fee of € 6.50 (2021) per item on the prescription (unless the pharmacy retail price is below the prescription fee, then the patient pays the pharmacy retail price). Vulnerable groups (e.g. low-income pensioners, people suffering from communicable diseases) are exempt. Furthermore, the spending of prescription fees is statutorily capped at 2% of the net annual family income.[24]

No aggregate consumption and spending data are readily available for the fragmented hospital sector. For the outpatient sector, high-level data are published (e.g. prescriptions at ATC-2 level).[25]

Results and effects of pricing and reimbursement

The Austrian National Public Health Institute has regulatory been carrying out medicines price comparison studies, including studies to monitor the prices of medicines that account for high financial burden for public payers. These price comparisons for high-cost medicines (i.e. medicines of high prices and/or high volumes) have consistently shown the same pattern over the last decade: Austrian ex-factory prices of outpatient high-cost medicines usually ranked above the EU average, whereas Austrian prices for high-cost medicines for inpatient use were frequently the highest of all EU Member States.[26-28] This tends to suggest that the policy framework at ex-factory price level for outpatient medicines based on external price referencing for new outpatient medicines and internal price referencing (price link for off-patent medicines) and a strict HTA process has been successful in keeping medicines prices sustainable. However, as Austria is among the first launch countries, it is imperative to regularly review prices in the external price referencing policy.[29] Austria's high prices of medicines used in hospitals likely result from the lack of price regulation and systematic HTA in this sector. Additionally, pharmacy mark-ups which have not been changed since 2003 have also always ranked high in European comparison.[26-28] Critics of medicines price comparisons and of price regulation have been arguing that purchasers pay less due to confidential deals in managed-entry agreements. However, this may also be the case for other countries. In addition, studies concluded that Austrian hospital procurers tended to be granted the same price across the country and that for some medicines (with alternatives) higher discounts could be agreed whereas it remains difficult to obtain reasonable discounts on some monopoly products.[30-32]

A second major deficit in the Austrian pharmaceutical system concerns the low uptake of generic and biosimilar medicines. This is likely linked to missing demand-side measures. Austria is the only EU Member State which has neither generic substitution nor prescribing by INN.[33] Over the years, several studies have shown the missed cost-savings potential for off-patient medicines in Austria.[34-36]

To conclude, Austria has overall a strong pharmaceutical regulation and policy framework for medicines. However, there are major gaps with regard to the hospital sector and the off-patent market which need to be urgently addressed since they limit affordable patient access to medicines.

Additional Information

In the EU, marketing authorisation has been harmonized: Marketing authorisation can either be centralised or attained by mutual recognition.[12] National marketing authorisation is possible but does no longer play a role in practice.[37]

Under the centralised marketing authorisation, a pharmaceutical company submits a single marketing authorisation application to the European Medicines Agency (EMA) whose Committee for Medicinal Products for Human Use (CHMP) carries out a scientific assessment of the application. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU Member States. Centralised marketing authorisation is compulsory for human medicines containing a new active substance to treat human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS), cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, viral diseases, medicines derived from biotechnology processes, such as genetic engineering, advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and orphan medicines (medicines for rare diseases). It is optional for other medicines containing new active substances for indications, that are a significant therapeutic, scientific or technical innovation and whose authorisation would be in the interest of public health at EU level. In practice, the vast majority of new, innovative medicines pass through the centralised authorisation procedure.[12]

For medicines outside the scope of the centralised procedure, a pharmaceutical company may request either the mutual-recognition procedure, whereby a marketing authorisation granted in one Member State can be recognised in other EU countries, or the decentralised procedure, whereby a medicine that has not yet been authorised in the EU can be simultaneously authorised in several EU Member States.[12]

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