

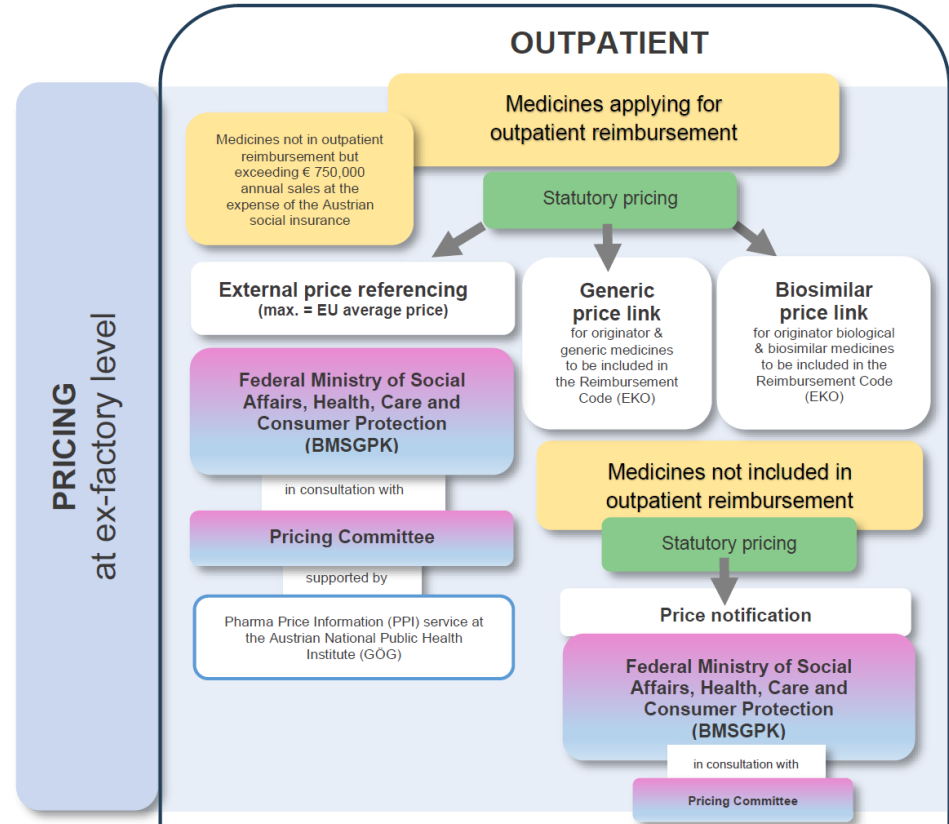
Pricing Committee and Appraisal Board

Austrian pharmaceutical system

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Pricing for outpatient medicines



Pricing for outpatient medicines / Statutory pricing

- **External price referencing** is applied for **reimbursable medicines** (those for which an application for inclusion into the Code of Reimbursement (EKO) was submitted)
 - NEW (since 2017): applied to medicines not included in the Code of Reimbursement whose sales at the expense of the social health insurance exceed the threshold of € 750,000 in the 12 preceding months
- **Price notification** for other medicines
 - To be notified to the Pricing Committee
 - If notified price is considered too high in the context of the Austrian economy → MoH can officially start a price setting process;
If such a process has not been launched within six weeks, the proposed price will automatically be granted

Pricing committee (Preiskommission)

- Hosted at the Federal Ministry of Social Affairs, Health, Care and Consumer Protection
- Members:
 - other Federal Ministries
 - the “social partners” such as the Federal Chamber of Commerce and the Federal Chamber of Labour
- Task: to calculate the EU average price based on price data submitted by the marketing authorisation holder

External price referencing / 1

- Reference countries: all other 26 European Union (EU) Member States
- Calculation method: benchmark price must not exceed the EU average (specifications for inclusion in EKO (boxes))
- Submission of price data by the manufacturer, with possibility for validation
 - Pricing Committee can request GÖG to review this price information (based on General Social Insurance Law (Allgemeines Sozialversicherungsgesetz / ASVG))

The EU average price serves as basis for further negotiations of the Austrian Social Insurance with the pharmaceutical company on the reimbursement price

External price referencing / 2

- **Minimum** of price data from two EU Member States is required to calculate the benchmark price
- A price is determined within six months upon receipt of a company's price application
- **Price evaluations** are mandatory:
 - 18 months after the first time a price was set
 - 24 months after the second time a price was set
 - another re-evaluation is possible 18 months after the third time a price was set

Appraisal Board / 1

- Issue: **no national (full) HTA process for medicines used in hospitals**, leading to possible discrepancies in access across regions
- Pilot of a **“Spitals-HEK”** (Hospital Pharmaceutical Evaluation Board)
 - Transferring components of outpatient HTA to evaluate three medicines for hospitals
 - With support of Austrian Social Insurance
 - Pilot but no binding value

Appraisal Board / 2

- Since 2024: **legal basis** exists to establish an Appraisal Board
 - For selected medicines in hospitals and
 - For selected medicines at the interface with the outpatient sector
- 2024: Currently **implementation** ongoing
 - Development of ToR
 - Stakeholder event (16 April 2024)
 - First HTAs to be commissioned from Q3/2024

Appraisal Board / 3

- Ensuring **fast and equitable access** to effective and specialised medicines
- Ensuring **uniform and appropriate use of high-priced and specialised medicines** throughout Austria
- Efficient **use of high-priced and specialised medicines**, which should result in faster and consistent inclusion into hospital pharmaceutical formularies

Appraisal Board - tasks / 4

- **Selection of medicines** for which the Appraisal Board issues recommendations is to be done in accordance with criteria as defined in the Hospital Law (KAKuG)
 - Nominated representatives of Regions and Social Insurance can propose medicines to be dealt with by the Appraisal Board
 - Appraisal Board has to take a decision on whether or not to deal with this medicines
- **Determination** of whether or not the proposed medicine is **affiliated to the hospital sector or to the interface** between the outpatient and hospital sector
- Development of transparent and comprehensible **recommendations** and their publication
- **Re-evaluation** of recommendations