

AUSTRIA

Recent and planned developments in pharmaceutical policies 2022/2023

CHANGES IN PRICING

Generics and biosimilars:

- Medicines of the same active substance included in the green box of the outpatient reimbursement list (having to be priced at the level of the cheapest alternative plus max. 20% (instead of 30% as of 2022, "Preisband") having the prescription fee as limit.
- The generic and biosimilar price link expires 31 Dec. 2023.

2023

Medicines outside of out-patient reimbursement list (EKO):

For medicines which are not included in the EKO but exceed a sales worth of € 750,000 (at ex-factory price basis) at the expense of the Austrian social health insurance during the last twelve months, prices are set ex-post based on EPR. If the EU average price determined by the Pricing Committee is lower than the price that was set by the marketing authorisation holder, the company has to repay the difference from the point in time when the turnover threshold was first exceeded. An **additional 6.5 %** to the EU average price has to be deducted since 01 April 2022.

1 April 2022 –
31 Dec 2023

Medicines included in the out-patient reimbursement list:

The Federal Ministry of Social Affairs, Health, Care and Consumer Protection published an [updated version](#) of the regulation on Procedural Rules for Calculation of the EU average price of the Pricing Committee following some changes in statutory rebates in other countries (Germany) which need to be considered in the pricing decision.

1 Feb 2023

CHANGES IN REIMBURSEMENT

Increase of prescription fee: 6.85 Euro (in 2022 it was 6.65 Euro)

1 Jan 2023

Special fund for Zolgensma® and Luxturna®:

Continuation of funding of Zolgensma® and Luxturna® through a separate fund jointly decided by the federal state, provinces and social insurance. Further expansions of the funding for high priced drugs (e.g. gene therapies) in negotiation.

1 Jan 2023

OTHER CHANGES

INN prescribing:

Reform process on-going on possible implementation of INN prescribing.

2023

Pilot project on medication analysis in community pharmacies:

Pilot project was started in 10 community pharmacies in Vienna to analyse the medication of patients affected by polypharmacy in a structured way. A roll-out to all community pharmacies is planned for 2024.

2022/2023

SPECIAL TOPIC:

Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

- 1) **Medicine shortages:**
 - National register to report shortages: in place (since 2020 mandatory) For medicines reported for shortages, an (optional) export ban can be mandated. These export bans are listed in an [additional registry](#).
 - Medicine reserves supplies: in preparation (new in 2023!)
 - Export ban / notification for medicines targeted by shortage: see above
 - Regulatory measures: no changes
 - Financial measures: no changes
 - Stakeholder involvement: Task Force on shortages involving all stakeholders (in place since several years)
 - Other: discussion on unsustainably low prices (new in 2023!); shortages of antibiotics are closely monitored; a medicine shortage does not automatically mean that there are no treatments for patients available
- 2) **Price increases:**
 - a) medicines included in the out-patient reimbursement list: The pharmaceutical company submits an application to the Austrian Social Insurance (DVS). The application is evaluated within 90 days.
 - The company has to justify the increase from a pharmacological, medical/therapeutic, and health economic point of view. Price increases are only possible 24 months after the inclusion in the out-patient reimbursement list or 24 months since the last price increase. Criteria: medical need, therapeutic alternatives, extent of the latest price increases, change of the consumer price index, EU-average price- It leads to a case-to-case decision.
 - Increase in number of requests was observed: in 2022 significant increase to 116 requests; in 2023: already 47 requests received by 03/03/23
 - b) medicines outside out-patient reimbursement list: free pricing, price notification procedure to MoH
 - c) medicines inpatient: no pricing regulations set, negotiations and procurement, price increase requests due to inflation
- 3) **Introduction or discussion of other measures related to current challenges (high inflation rates, budget caps, high-priced medicines, introduction of production sites in Europe, etc.):**
 - Develop national coordination for patient and/or disease registers in Austria.
 - Strengthen and improve enforcement of supply obligations on marketing authorisation holders and wholesalers of critical and essential medicines.
 - Develop an assessment board for medicines used in inpatient setting
 - Assess the potential for improved data collection on rational use of medicines.
 - Build a diverse funding structure for basic and applied research on unmet medical needs in Austria
 - Ensure resilient availability of (future) critical medicines by strengthening production through strategic expansion and diversification