

SWEDEN

Recent and planned developments in pharmaceutical policies 2023

CHANGES IN PRICING

Market Entry Agreement status

- The regions are health care providers and collaborate in a joint process for the introduction of new medicines in Sweden. A total of 63 products were included in the benefits scheme and subject to a MEA for either part or all of 2022. For 7 products, either the regions or the pharmaceutical company have chosen not to prolong or renegotiate the MEA. TNF-alfa inhibitors are not subject to MEA after September 2021.

By January 1st 2023, 56 products were subject to a MEA within the benefits scheme.

CHANGES IN REIMBURSEMENT

Patient co-payment in 2023

- Patients and the state/regions share the costs of pharmaceuticals included in the benefit scheme. Over a 12-month period, patients pay the full amount of pharmaceutical costs up to SEK 1 300 (€ 115), where a stepwise subsidy scheme begins. After reaching the high-cost ceiling of SEK 2 600 (€ 230), patients' pharmaceuticals are fully subsidised.



OTHER CHANGES

TLV's annual international price comparison of pharmaceuticals 2022

TLV monitors and analyses the development of pharmaceutical prices in Sweden and internationally. This year's report compares Swedish prices with 19 other European countries and among other things evaluates relative prices throughout the lifecycle of pharmaceutical products. Swedish relative pharmaceutical prices are lowest after a product has been 15 years on the market, which roughly corresponds to the date of expiry of a pharmaceutical's patent. The report can be found at this [webpage](#). The English translation of this year's report will be published in March.



Pharmacy services

As part of a governmental assignment to TLV, a national pilot study with a pharmaceutical service aiming to improve asthma and COPD patients' inhalation technique has been completed and evaluated in 2022. Pharmacists at 150 community pharmacies and at one e-pharmacy were involved. The pilot was successfully conducted and half of the patients receiving the service needed support with their inhalation technique from the pharmacist. A second pilot which focuses on counselling and motivating patients beginning chronic medicine treatments is currently being carried out and evaluated by researchers at Uppsala University. Results are expected in 2024. TLV has proposed a process and model for public funding of pharmaceutical services and is currently addressing regulatory aspects and policies.



New country profile

General information about pricing, reimbursement and procurement of pharmaceuticals in Sweden is available in the PPRI country profile of 2023, please see [Pharma Profile Sweden 2023](#).

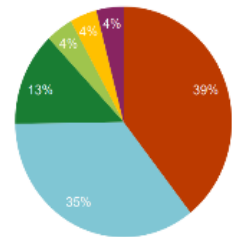


SPECIAL TOPIC:

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

Medicine shortages

- a) The Swedish Medical Products Agency (SMPA) is increasing its efforts in market monitoring/surveillance and is developing new forms of collaboration with different parties within the field of both pharmaceuticals and medical devices, [more information \(in Swedish\)](#)
- b) A list of ongoing medicinal shortages, recommended alternative products, shortage durations etcetera is updated daily and available on the SMPAs webpage, [link \(in English\)](#)
- c) Antibiotics shortages vary over time and last from a few days to several years.
Causes for shortages in 2021 of ATC J01:
 - Manufacturing capacity (39%)
 - Increased demand (35%)
 - Lack of active product ingredient (13%)

**Price increases:**

- a) Out-patient medicines: The pharmaceutical company applies for a price increase to TLV. The application is evaluated within 90 days.
 - The company should explain the reason behind the price increase application, i.e. explain why they can't supply the product to the current price. The company needs to justify the price increase from a cost perspective and the new price needs to be reasonable in relation to their costs.
 - When determining if a price increase should be granted TLV also considers how great the medical need is for the product, if there are therapeutic alternatives and the risk that the medicine will otherwise leave the Swedish pharmaceutical benefits system.
 - A rise in requests for price increases has been observed in recent months.
- b) In-patient medicines: Prices are based on agreements between pharmaceutical companies and the different regions in Sweden. The agreements are usually valid for two to four years, but different arrangements can occur.

Other measures:

- a) Pharmaceuticals with generic competition have a ceiling price, which is the highest allowed price in every substitution group. The system to determine ceiling prices was designed in 2011 and has contributed to keeping the prices at a low level without much fluctuation. However, the system is not designed to handle changed market conditions such as increased costs or exceptionally high inflation rate. For this reason, TLV has decided to review the ceiling price system in order to create a new system that is sustainable over time and will work in times of economic change, secure a stable supply of pharmaceuticals and well-functioning generic competition, and at the same time contribute to a cost-efficient use of pharmaceuticals.
- b) Due to the current high inflation rate, TLV has decided to urgently increase some of the ceiling prices for medicines with generic competition in May 2023, before the new ceiling price system has been implemented. To get an increased ceiling price the substitution group needs to meet certain criteria concerning the availability of the articles in the group and the price of the cheapest available article in the group.