Price increases of prescription drugs in Sweden – In which cases are they approved?

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Background

In Sweden, the initial price of a reimbursed medicine is determined at the time of the reimbursement decision. After that, the Dental and Pharmaceutical Benefits Agency (TLV) only grants price increase applications for reimbursed drugs in exceptional cases. If a medicine does not have a ceiling price (i.e., no generic competition) and the marketing authorization holder wants to raise the price, the following criteria must be met for TLV to accept the price increase:

Criteria 1: The drug is an urgent treatment option because it is used to treat a non-trivial condition that poses risks to the patient's life and future health. There are patients who risk being left without alternative treatments of a similar kind if the drug disappears from the Swedish market. **Criteria 2:** There is a great risk that the drug will disappear from the Swedish market, or that availability will be greatly reduced if the price increase is not granted.

Methods

The TLV database for reimbursement decisions was used to identify decisions regarding price increases of prescription drugs between 1 January 2019 and 15 June 2022. The published decision documents were qualitatively assessed, identifying TLV's arguments related to the decision outcome. The drugs were classified by ATC categories and the relative price increases (pharmacy selling prices) of the approved decisions were quantified.

Results

During the study period, 56 medicines were subject to price increase applications, of which 39 were approved. This included a wide range of medicines such as human immunoglobulin therapies, therapies for depression, schizophrenia, and anxiety as well as therapies for patients with high blood pressure. Table 1 shows the approval rate and the average price increases of all the included decisions, classified by ATC categories.

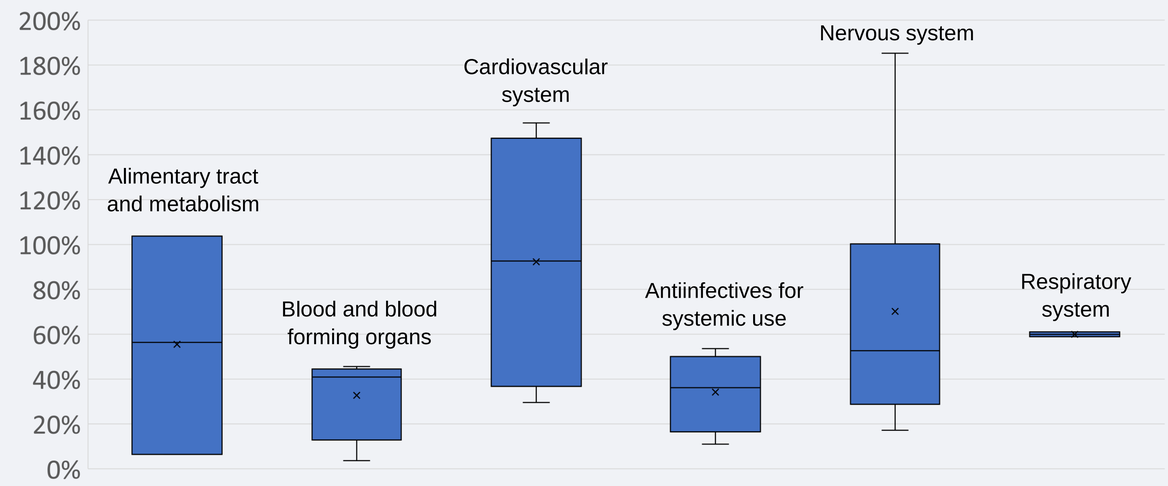
Table 1: Approval rate and average price increase of TLV price increase decisions 1 Jan 2019- 15 Jun 2022

Type of Drug	Total Decisions	Approved decisions	Mean price increase
Alimentary tract and metabolism	**7**	**3 (43%)**	**56%**
Antidiarrheals, intestinal anti-inflammatory/anti-infective agents	2	1	
Bile and liver therapy	2	0	
Drugs for constipation	2	1	
Stomatological preparations	1	1	
Antiinfectives for systemic use	**13**	**9 (69%)**	**34%**
Antibacterial drugs	7	3	
Immune sera and immunoglobulins	6	6	
Antiparasitics, insecticides and repellents	**1**	**1 (100%)**	**68%**
Blood and blood forming organs	**4**	**4 (100%)**	**33%**
Cardiovascular system	**7**	**4 (57%)**	**92%**
Beta blocking agents	1	0	
Calcium channel blockers	2	2	
Cardiac therapy	1	1	
Diuretic drugs	3	1	
Musculoskeletal system	**3**	**1 (33%)**	**65%**
Nervous system	**15**	**12 (80%)**	**70%***
Analgesic drugs	1	1	
Antiepileptic drugs	2	2	
Antiparkinson drugs	1	1	
Other nervous system drugs	1	1	
Psychoanaleptics	1	1	
Psycholeptics drugs	9	6	
Respiratory system	**2**	**2 (100%)**	**60%**
Sensory organs	**2**	**1 (50%)**	**25%**
Systemic hormonal preparations	**1**	**1 (100%)**	**30%**
Various ATC structures	**1**	**1 (100%)**	**29%**
Grand Total	**56**	**39 (70%)**	**58%**

* One extreme outlier decision with a price increase of 565% was excluded.

The relative price increase varied between treatments and indications. Figure 1 shows the range of the relative price increases of the different ATC categories.

Figure 1: Price increases of the approved decisions



ATC categories with at least two approved decisions were included. One extreme outlier with a price increase of 565% was excluded. Four other decisions were excluded as the relative price changes were not disclosed in these decision documents.

For all the 39 approved applications, TLV considered that the applying company sufficiently had demonstrated that both criteria were fulfilled. However, for the rejected applications, in 76% of the cases, TLV argued that criteria 1 was not met and in 29% of the rejected applications, TLV mentioned that criteria 2 was not fulfilled.

TLV arguments regarding criteria 1:
In none of the applications, TLV considered that the drug was used to treat a trivial condition. Instead, the availability of alternative treatment options was the most frequently used argument. This included the potential challenges linked to treatment interruption or switching including the mode of administration, intolerance to treatment alternatives, and side effect profiles.

TLV arguments regarding criteria 2:
TLV reviewed factors associated with the sales value of the drug including patient numbers, cost of production, and the initial price level compared to other European countries and comparable drugs in Sweden.

Discussion

Key interpretations:

- This study showed that the most common reason for rejection was related to criteria 1. The main argument used by TLV was the presence of treatment alternatives on the Swedish market. Therefore, the most crucial factor of the decision outcome will be if an applying company can demonstrate that patients risk being left without alternative treatments if the drug would disappear from the Swedish market.
- Fewer applications were rejected due to criteria 2. In these rejected submissions, TLV argued that the sales value of the drug was high or that the submitting company had failed to show that a price increase was needed to keep the drug on the market.
- The most common type of drugs included in the decision database were psycholeptic drugs, antiinfective drugs for systemic use, alimentary tract and metabolism drugs, and cardiovascular system drugs. Although most applications resulted in a price increase, the approval rate and the relative price increase varied between the ATC categories.

Limitations: As companies are allowed to withdraw their submissions prior to TLV's decision, it is not possible to access all applications and there may be a bias towards more positive decisions being published than rejections.

Conclusions

Most of the available price increase applications resulted in a price increase. While the relative price increase varied between medicines, common factors of the decision outcome were identified, including the availability of treatment alternatives and the sales value of the drug.