TLV
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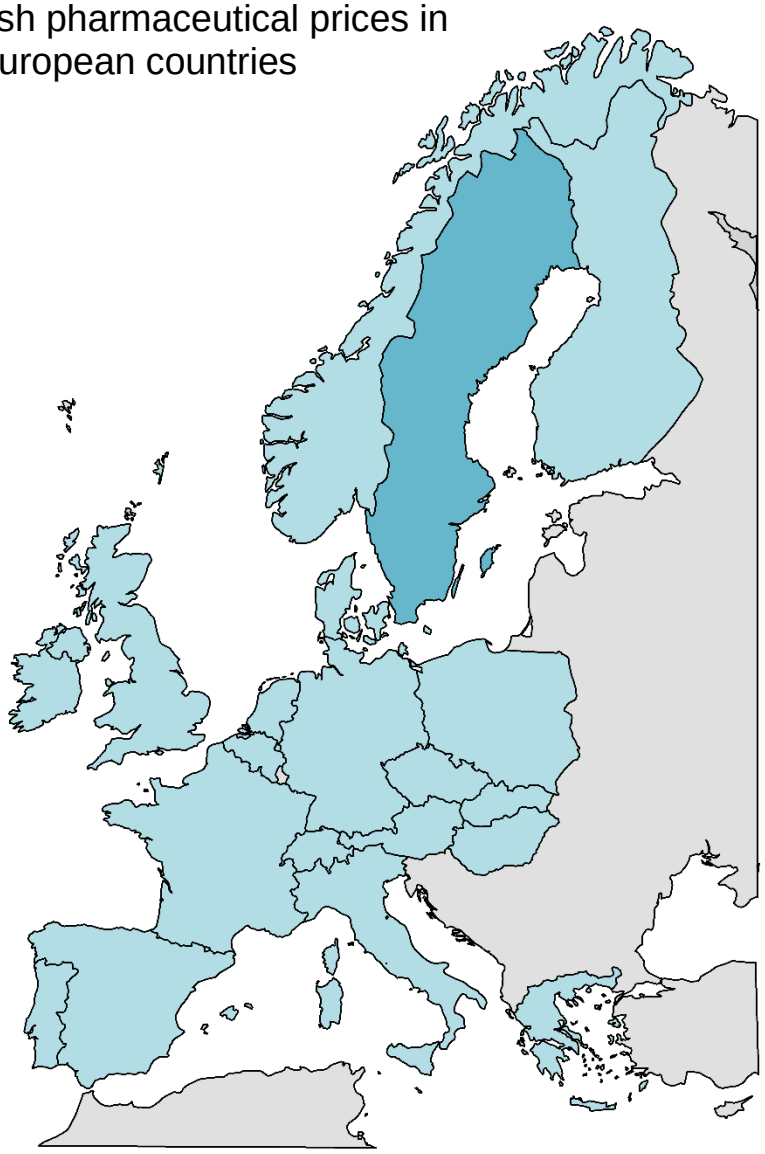
LÄKEMEDELSFÖRMÅNSVERKET

International price comparison 2022

An analysis of Swedish pharmaceutical prices in relation to 19 other European countries



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Preface

The Dental and Pharmaceutical Benefits Agency's (TLV's) mandate includes monitoring and analysing the price development of pharmaceuticals from an international perspective.

TLV presents the results of the analysis, which is based on price and volume data for the first quarters during the period 2014 to 2022 in Sweden in comparison with 19 other European countries. The analysed segments are pharmaceuticals without generic competition and pharmaceuticals with generic competition. Pharmaceuticals with competition include pharmaceuticals available as substitutable pharmaceuticals in the product-of-the-month system as per March 2022.

The working group for the report included Christoffer Karlsson, Marie Orre and Jonas Nilsson.

The report should be seen as a basis for TLV's continuous monitoring of the dynamics of Swedish prices and how Swedish prices relate to prices in other countries.

Agneta Karlsson
Director General

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Summary

This report is part of TLV's mandate to monitor developments in the Swedish pharmaceutical market from an international perspective. The report is the ninth of its kind.

The report compares pharmaceutical prices in Sweden with prices in 19 other European countries. The price comparison is based on list prices (pharmacy purchase price, AIP), which means that any agreements on discounts on pharmaceuticals in different countries were not taken into account in the analyses. The focus of the report has been prescription pharmaceuticals. A division has also been made based on the competitive situation for a pharmaceutical, as the conditions vary greatly depending on whether there is generic competition.

The analyses in the report show that Sweden's relative pharmaceutical prices are the fifth lowest in the segment Pharmaceuticals without generic competition and the lowest in the segment Pharmaceuticals with generic competition in relation to the 19 comparison countries.[1] Prices in Sweden have fallen in relation to prices in the other countries during the period studied (2014–2022).

One important explanation for the falling prices, especially for pharmaceuticals without generic competition, is the weaker Swedish krona. As AIP is set in SEK, a weaker currency exchange rate for the Swedish krona leads to lower Swedish prices in relation to other currencies. If the exchange rate effect is removed, Swedish prices are largely unchanged in relation to other countries over time.

A life cycle analysis shows that Sweden's pharmaceutical prices are, on average, slightly below the EU average during the first five years after market introduction. Swedish pharmaceutical prices remain around the European average during the subsequent five years, and then rise above the EU average between year 10 and year 15. After 15 years on the market, which roughly corresponds to the date of expiry of a pharmaceutical's patent, Sweden's pharmaceutical prices, on average, fall below the EU average. Depending on which years, pharmaceutical classes and countries are included in the input data for the life cycle analysis, it is mainly the size of the percentage difference in price compared to the European average that changes, not the overall pattern.

During the entire period 2014–2022, prices of pharmaceuticals in Sweden in the product-of-the-month system have been among the lowest in Europe. In 2022, Sweden's prices for pharmaceuticals with generic competition were approximately 50 percent lower than the average for the other 19 countries.

[1] A three-year rolling average for exchange rates has been used to convert local currencies to euro.

Terms and concepts

Active substance – The substance in a pharmaceutical product that gives it its medical effect.

ATC – *Anatomical Therapeutic Chemical Classification, (ATC*) is a pharmaceutical classification system. The ATC system has 14 main groups into which pharmaceuticals are classified based on their main indication.

A Alimentary tract and metabolism
B Blood and blood forming organs
C Cardiovascular system
D Dermatologicals
G Genito urinary system and sex hormones
H Systemic hormonal preparations, excluding sex hormones and insulins
J Antiinfectives for systemic use
L Antineoplastic and immunomodulating agents
M Musculo-skeletal system
N Nervous system
P Antiparasitic products, insecticides and repellents
R Respiratory system
S Sensory organs
V Various

Bilateral price index – The same product needs to be available in both Sweden and one of the comparison countries to be included in the price index against that country.

Ceiling price – The maximum accepted price (pharmacy purchase price/unit) of a pharmaceutical in a pack size group.

Cross-sectional price index – The same product needs to be available in several countries to be included in any of the countries' price indices. The threshold, known as the matching rate, has been set at 40 percent in cases where cross-section indices are used. This means that a pharmaceutical (substance, dosage form, and strength) needs to be available in at least eight other countries in addition to Sweden. In countries that do not have sales for a year of a pharmaceutical available in Sweden, an average of the countries for which price data are available is used.

Dosage form – Different forms of how a pharmaceutical can be delivered to the body, for example, via tablet, injection or patch.

ERP – External reference pricing, see IRP.

Ex factory – Sales price from the marketing authorisation holder. Costs for transport from the factory and other taxes and surcharges will be added.

Generic pharmaceutical – Pharmaceuticals that contain the same active substance, in the same dosage form, with the same strength, and producing the same medical effect as the original pharmaceutical product used as a reference product during the authorisation process.

Generic substitution/product-of-the month system – The pharmaceutical substitution that pharmacies must offer their customers when the pharmaceutical benefits scheme includes generic competition. Generic competition means that at least two pharmaceuticals that are substitutable pursuant to Section 21(1) of the Act (2002:160) on Pharmaceutical Benefits, etc. in a particular substitution group are offered for sale to retail pharmacies on the Swedish market. See also product-of-the-month.

Hospital pharmaceuticals – Pharmaceuticals procured by the healthcare system and administered within hospitals. In previous reports, this was called “inpatient pharmaceuticals”.

INN – Generic name – Like the chemical name, describes a substance. INN stands for *International Non-proprietary Name*. The purpose of generic names is to enable brand-independent communication about pharmaceutical substances. Generic names are established by several different countries and by the WHO.

IRP – International Reference Price – Pricing method in which the price(s) of a pharmaceutical in one or more countries is/are taken into account in the national pricing of pharmaceuticals. Common synonymous terms are International Reference Pricing (IRP), *External Price Reference* (EPR), *External Reference Pricing* (ERP) or simply reference pricing. The pricing method can be formal or informal/supporting, in combination with another method (e.g. assessment of benefit or value). Some countries employ the concept of *internal* reference pricing, which is why, in some literature, the acronym IRP is used differently than in this report.

List price – Price paid without regard to discounts or repayments. Corresponds in this report to determined pharmacy purchasing prices (AIP) in Sweden. When countries, including Sweden, are referred to as a group, the term list prices is also used to describe Sweden's prices (AIP).

Managed entry agreement – Collective name for agreements by which the cost of using a pharmaceutical is reduced, such as risk-sharing agreements, discount and repayment agreements. In Sweden, a managed entry agreement is a civil law agreement between a pharmaceutical company and individual regions that is drawn up within the framework of, or as a result of, TLV's case management (known as tripartite deliberation). The managed entry agreement regulates one or more circumstances related to the actual use of a pharmaceutical.

Managed introduction – in Sweden called *National managed introduction of new pharmaceuticals* and is coordinated by the New Therapies (NT) Council. Sweden's regions collaborate on which new pharmaceuticals to introduce in healthcare.

Original pharmaceutical – The first pharmaceutical on the market that contains a particular active substance. These pharmaceuticals are under patent protection and are thus not subject to competition from generic equivalents for a number of years.

Pharmaceutical benefits – A pharmaceutical included in the pharmaceutical benefits scheme is subsidised and included in the high-cost protection system, which limits how much a patient has to pay for their pharmaceuticals. The

provisions on pharmaceutical benefits can be found in the Act (2002:160) on Pharmaceutical Benefits, etc. and in statutes enacted pursuant to that Act.

PPP – Pharmacy purchase price (Sw. AIP) – The pharmacy purchase price in SEK. Determined by TLV.

Prescription medicines – Pharmaceuticals that have been prescribed and are dispensed at a retail pharmacy.

Product – A pharmaceutical with the same substance, dosage form and strength.

Product-of-the-month (PV) – In Sweden, products-of-the-month are the available generic substitutable pharmaceuticals with the lowest prices that pharmacies must offer their customers when substituting pharmaceuticals. Each month, the product in each package size group with the lowest sales price per unit that the pharmaceutical company has confirmed can be provided to the entire market with a sufficient shelf life for the entire price period becomes the product-of-the-month. See also Generic substitution/product-of-the month system.

PRP - Pharmacy retail price (Sw. AUP) – The pharmacy retail price in SEK. Determined by TLV.

PV system – see *Product-of-the-month (PV).*

Relative prices – Prices in relation to average prices. If relative prices in Sweden rise, it means that Sweden has become more expensive in relation to average prices. This may be due to Sweden's prices rising, or other countries lowering their prices and Sweden maintaining the same level.

Repayment – a form of reimbursement paid in arrears. In Sweden, the pharmaceutical companies pay a repayment to the regions based on what is stated in the managed entry agreements. Internationally, often referred to as a discount.

Risk-sharing agreements – Agreements in which the final cost for the use of a pharmaceutical depends on future outcome. Often used for new expensive pharmaceuticals where the therapeutic benefit is uncertain.

Substitutable pharmaceuticals – Pharmaceuticals that contain the same active substance, in the same dosage form, with the same strength, and give the same medical effect, and that the Swedish Medical Products Agency has determined are substitutable with one another.

The segment Pharmaceuticals with generic competition (in the PV system) – Includes all pharmaceuticals included in the product-of-the-month system during a corresponding period of the time-series.

The segment Pharmaceuticals without generic competition – Includes products for which there has been no competition between two different substitutable pharmaceuticals in Sweden. However, competitive conditions may differ between the various countries in the price comparison.

UFBLI – Selected mainly biological, anti-inflammatory compounds.

1 Introduction

1.1 Assignment

The Ordinance (SFS 2007:1206) with instructions for TLV states, inter alia, that the Agency shall monitor and analyse developments in other countries and make use of their experiences, compare the price level in Sweden with prices in other countries for relevant products in the pharmaceutical sector, and monitor price development in the sector from an international perspective. The comparisons in the report are based on list prices. In Sweden, list prices consist of the pharmacy purchase price (AIP) determined by TLV.

The purpose of this report is to compare and analyse Sweden's pharmaceutical prices in relation to 19 other European countries. In addition to the official prices analysed in the report, there are confidential agreements that regulate the cost of certain pharmaceuticals, which imply lower realised costs than indicated by the list prices. In Sweden, there are managed entry agreements between regions and pharmaceutical companies that involve repayment of parts of the pharmaceutical costs. Thus, society's pharmaceutical costs are affected by repayments from managed entry agreements. The effect of different countries' varying repayment agreements is not captured in this report, nor is it intended to be.

Table 1. Countries included in the analysis

Austria	Italy
Belgium	Norway
Czechia	Poland
Denmark	Portugal
Finland	Slovakia
France	Spain
Germany	Sweden
Greece	Switzerland
Hungary	The Netherlands
Ireland	United Kingdom

The report primarily uses exchange rates calculated as a three-year rolling average to avoid temporary exchange rate fluctuations while retaining the effects of long-term changes.[2] The prices analysed in the report for the years 2014-2022 are based on data for the first quarter of each year, while the number of units sold, which is used to weight average prices, covers sales between March each year and 12 months back in time (rolling 12 months).

[2] Read more about the impact of the exchange rate on the analysis in *Appendix 1 (Section 1 Exchange rate).*

1.2 Outline

Under the heading *Methodology and data (Section 1.3)*, there is a summary of the report's methodology, choice of exchange rate period, and data sources. This is followed by a section on the pharmaceutical market in general and information on pricing and subsidy systems for the selected countries.

The *Price comparisons section (Section 3)* is divided into five sections. The first section is an in-depth study of the pharmaceuticals' life cycles, where prices are analysed over the life-cycle of a pharmaceutical starting from the date of marketing authorisation. This is followed by a more detailed description of pharmaceuticals without generic competition (outside of the product-of-the-month system, hereinafter called the PV system) and then a more in-depth focus on pharmaceuticals with generic competition (within the PV system). This is followed by an in-depth analysis focusing on selected pharmaceutical classes from a Nordic perspective. Section 3 concludes with a bilateral price comparison in which the sales volumes of all countries are used when calculating the volume-weighted averages.

The report concludes with a discussion of the main results of this year's study and information on TLV's work going forward.

The report has two appendices. The first appendix (*Appendix 1: Sensitivity analyses*) presents a number of sensitivity analyses. A more detailed description of the analytical methods used is provided in *Appendix 2: Methodology and data*.

1.2.1 Delimitation

The assignment does not include determining whether Swedish pharmaceutical prices are at the desired level, nor how to design potential changes to reach such a level.

The analyses cover prescription pharmaceuticals dispensed in retail pharmacies, which corresponds to about two-thirds of total pharmaceutical sales in Sweden. However, the proportion of pharmaceuticals managed as hospital pharmaceuticals versus prescription-based varies considerably between countries.

1.3 Methodology and data

1.3.1 Description of data sources

Methodology and data are described briefly in this section. A more in-depth account can be found in *Appendix 2: Methodology and data*.

TLV uses price and sales statistics from the company IQVIA for the years 2014 to 2022. The price data are taken from the first quarter of each year, while sales statistics cover sales between March of each year and 12 months back in time.

The selection consists of prescription medicines for human use in Sweden that are included in the pharmaceutical benefits scheme, and with the highest sales volumes. In addition, there are substances that have relatively low sales in Sweden but high sales in Europe, as well as new substances.[3] By complementing the selection with European top sellers, the comparison becomes fairer, as more relevant pharmaceuticals are compared. There is sales data for a total of 829 substances and 6,742 pharmaceuticals over the entire time series and across all comparison countries.[4] While the analyses will essentially be based on pharmaceuticals which are sold in Sweden, in some contexts pharmaceuticals not sold in Sweden will also be included (this applies to analyses where other countries' price dynamics or relative prices are analysed as well as in Section 3.5, where an alternative price index is used).

The market has been divided into pharmaceuticals without and with generic competition. Pharmaceuticals with generic competition include pharmaceuticals included in the Swedish PV system, which means that a pharmaceutical has generic competition and is substitutable in pharmacies.[5] Divided in accordance with this definition, the analysis includes[6]:

- **Pharmaceuticals without generic competition that had sales in 2022:**

  All countries: 798 substances and 5,108 pharmaceuticals.

  Sweden: 543 substances and 1,312 pharmaceuticals.

[3] EFPIA's (2021) WAIT Indicator
[4] Pharmaceuticals are defined as a combination of substance, dosage form and strength.
[5] TLV (2022) Periodens varor
[6] A substance can be found in both the segment with competition and the segment without competition. This is because different forms and strengths of the same substance may have different competition status. This means that the sum of the two segments' unique substances will be greater than the total number of unique substances across both segments.

- **Pharmaceuticals with generic competition that had sales in 2022**:
  All countries: 205 substances and 669 pharmaceuticals.
  Sweden: 202 substances and 637 pharmaceuticals.
- **All pharmaceuticals over the entire time series:**
  All countries: 829 substances and 6,742 pharmaceuticals.
  Sweden: 686 substances and 2,357 pharmaceuticals.

In Sweden pharmaceuticals without generic competition during Q1 2022 accounted for approximately 83 percent of the sales volume (AIP), and pharmaceuticals with generic competition accounted for approximately 17 percent. IQVIA's data covers around 90 percent of sales in Sweden in 2022.

1.3.2 Method

One challenge with price comparisons between different countries is that not all countries use the same pharmaceuticals as Sweden. For example, countries may use different pharmaceuticals to treat the same condition, or a pharmaceutical may be approved for subsidy in only some of the countries included in the comparison. The proportion of the same pharmaceutical used in two countries being compared is called matching rate. The higher the matching rate, the higher the proportion of pharmaceuticals in Sweden that are found in a comparison country.

The report uses three methods to compare prices. The methods are similar in some respects, but differ in how they handle cases when one or more pharmaceuticals are not found in the sales statistics of all countries:

- **Bilateral comparison**
  Prices are only compared for the pharmaceuticals available in an individual country and in Sweden. For example, if Finland uses 59 percent of the pharmaceuticals used in Sweden, the price comparison only covers these pharmaceuticals. Pharmaceuticals with very low sales in relation to the reference country's local market are excluded. The bilateral comparison is partly affected by the fact that Swedish volumes are used. This is because pharmaceuticals frequently used in Sweden usually have a relatively low Swedish price.

- **Bilateral average**
  In addition to the bilateral comparison described above, an alternative measure that includes information from all countries' pharmaceutical use is also calculated. This measure, called the bilateral average, is calculated in such a way that the bilateral comparison is repeated for all combinations of countries, in pairs, i.e. that a bilateral index is calculated for all countries based on each country's own product basket. Finally, an overall average index is calculated, giving an index that takes into account the use of pharmaceuticals in all countries included in the comparison.

- **Cross-sectional comparison**
  This comparison assumes that all countries in the study have all the pharmaceuticals used in Sweden. If a country does not use a pharmaceutical, it is assumed that this country's price is the same as the average price of the

pharmaceutical in the countries that use it. To ensure that enough countries use a particular pharmaceutical, the pharmaceutical must have been sold in at least eight countries to be included in the comparison.

The cross-sectional comparison analysis is used to calculate the development of Swedish prices in relation to the European average. The bilateral price comparison instead describes price differences between individual countries and Sweden. Both the bilateral and cross-sectional price comparisons are based on Swedish volumes of each pharmaceutical. The bilateral average analysis takes the volumes of all countries into account. For more detailed information on the methodology, see *Appendix 2: Methodology and data*.

In the analyses that examine Sweden's relative pharmaceutical prices with the included comparison countries, pharmaceuticals are generally limited to those with sales in Sweden. If a pharmaceutical is sold on prescription in Sweden but not in any of the other 19 countries, it will not be included in these analyses either.

2 The pharmaceutical market

The healthcare systems in the countries being compared have both similarities and differences in how they price pharmaceuticals. This relates to factors such as the transparency in list prices, whether or not discount systems are institutionalised and incorporated into list prices, or if there are other agreements that result in certain list prices not fully reflecting the actual price of a pharmaceutical.

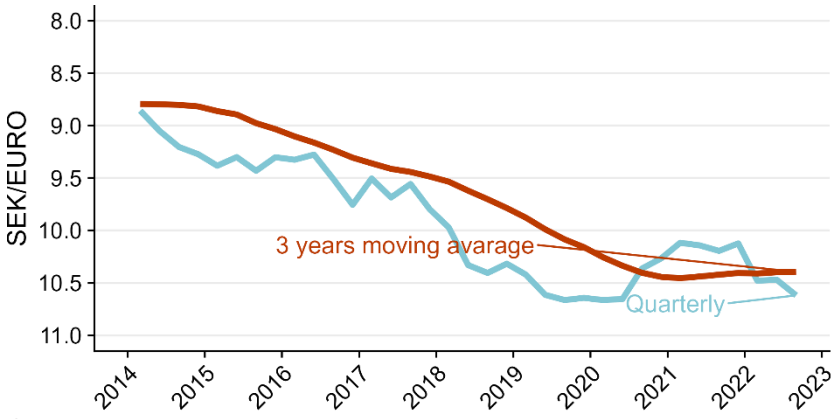
Globally, pharmaceuticals had sales of approximately SEK 10,787 billion in 2021, calculated as the price from the manufacturer. North America dominates the pharmaceutical market and accounts for 49.1 percent of total sales in the world market; Europe accounts for 23.4 percent; Africa, Asia (excluding Japan and China) and Australia combined account for 8.4 percent; China 9.4 percent; Japan 6.1 percent; and Latin America 3.7 percent.[7]

2.1 Exchange rate

For a number of years, the Swedish krona has fallen in value against the euro, which has also affected Swedish pharmaceutical prices compared with other countries. Between Q3 2020 and Q4 2021, the value of the krona in relation to the euro has strengthened somewhat, which affects the analyses presented in this report. To get a more balanced picture of Swedish relative prices, exchange rates have therefore been calculated as a three-year rolling average.

Figure 1 below shows the development of the Swedish krona quarterly and as a three-year rolling average to clarify the difference between the two methods.

Figure 1. Development of the Swedish krona, quarterly and in a 3-year rolling average, 2014–2022



Source: Eurostat
Note: SEK/EURO = the number of Swedish kronor per euro.

Figure 1 shows that the Swedish krona has strengthened (quarterly) since the latter part of 2020 up to Q4 2021. The three-year rolling average shows a continued downward trend over the same period, but at a declining pace, and then shows a

[7] EFPIA, The Pharmaceutical Industry in Figures 2022, indicates that global sales amounted to EUR 1,062,707 million in 2021. The average exchange rate for 2021 (10.15) was used to convert the figure to SEK.

slight upward trend in subsequent periods. As the three-year rolling average is the one predominantly[8] used in the report, the currency effect has continued to help keep Swedish relative prices of pharmaceuticals down, even during the period when the krona strengthened against the euro. In 2022, the Swedish krona again weakened against the euro, and in Q3 2022, the exchange rate of the Swedish krona is at a similar level as Q3 2020. This will have a limited impact in this year's report, which includes data up to Q1 2022, and given the three-year rolling average exchange rate used.

Figure 25 in *Section 1.1: Exchange rate* in *Appendix 1* shows the percentage change since the index year 2014 for the exchange rates of all comparison countries. Since 2014, the Swedish krona has depreciated against the currency of the majority of the comparison countries, with the exception of the Norwegian krone (NOK) and the Hungarian forint (HUF), measured at Q1 2022. On average, the Swedish krona has depreciated by 17 percent (quarterly) and 13 percent (3-year rolling average), measured at Q1 2022, compared to the index year 2014.

In some analyses, the exchange rate is fixed at the 2014 three-year average exchange rate over the entire time series. This means that, for each currency, the same exchange rate is used over the time series to convert prices into a common currency. This is then explicitly stated in the context of the figure. When the exchange rate is fixed, the data better describes the price changes different countries see in local currency and reflects whether there are price dynamics beyond exchange rates. See *Section 1.1: Exchange rate* in *Appendix 1* for further details.

2.2 Prescription pharmaceuticals and hospital pharmaceuticals

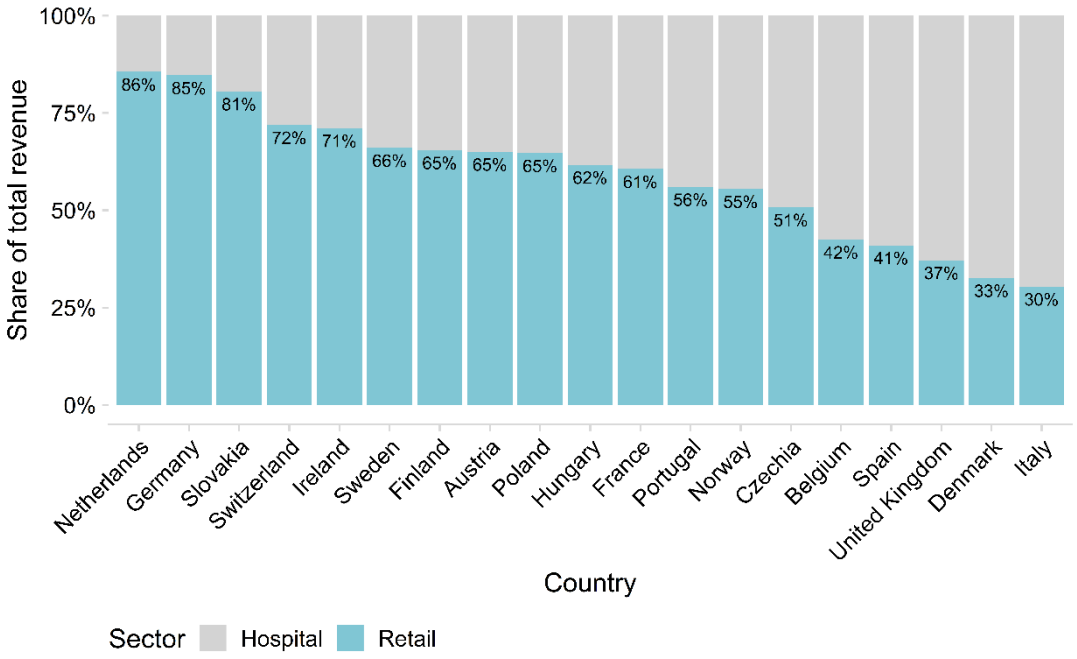
In Sweden, the majority of pharmaceutical use consists of prescription pharmaceuticals that are dispensed at retail pharmacies. The proportion of pharmaceuticals dispensed at retail pharmacies and in hospitals[9] differs between the countries included in the comparison. Comparisons that only include data from prescription pharmaceuticals should therefore be made with some caution. Depending on how pharmaceuticals are managed, by prescription at retail pharmacies or in hospitals, this type of comparison is more difficult if specific national circumstances are not known.

Figure 2 shows the percentage of total pharmaceutical sales in each country dispensed via prescription at retail pharmacies and in hospitals. On average, these 19 countries[10] manage about 59 percent of the total sales as prescribed pharmaceuticals dispensed at retail pharmacies. Italy, Denmark, the United Kingdom, Spain and Belgium have the lowest proportion of prescription pharmaceuticals disposed at retail pharmacies and a significantly higher proportion

[8] The three-year rolling average exchange rate is used in all analyses, unless otherwise specified.
[9] The report mainly uses the terms prescription pharmaceuticals and hospital pharmaceuticals to differentiate between pharmaceuticals that are prescribed and dispensed at retail pharmacies and pharmaceuticals that are procured by healthcare providers and administered in hospitals or elsewhere as part of a healthcare visit. In the data from IQVIA, these segments are referred to as “Retail” and “Hospital”.
[10] Greece has been excluded from the figure, as there is no available information on pharmaceuticals administrated in hospitals .

pharmaceuticals administrated in hospitals. In Sweden, about two-thirds are managed through prescriptions and one-third are handled in hospitals.

Figure 2. Percentage of pharmaceutical sales in AIP that is managed in hospitals and as prescription pharmaceuticals, by country



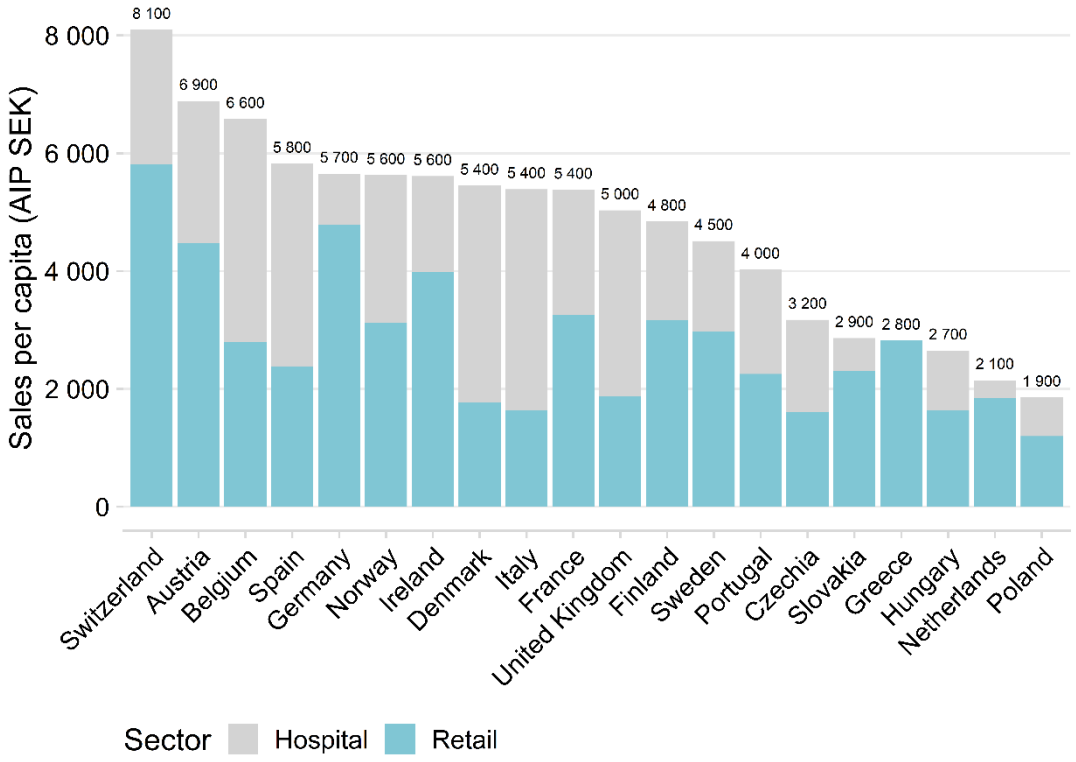
Source: IQVIA and TLV analysis.
Note: Data regards March 2022, 12-month rolling average. Greece has been excluded as there is no available information on pharmaceuticals administrated in hospitals.

In the 2019 report, prescription pharmaceuticals accounted for 75 percent of the share of total sales value in Sweden (sales March 2019 and 12-month rolling average), while the share for this year's report is 66 percent (sales March 2022 and 12-month rolling average). The difference is mainly due to how access to complete sales statistics from the Swedish eHealth Agency (EHM) has become more limited. IQVIA retrieves data from the wholesale level, supplemented by TLV. The change in application means that, for the purposes of this report, TLV cannot provide a complete picture of the pharmaceutical costs of pharmaceuticals administrated in hospitals in an international comparison.

Figure 3 shows the sales per capita in Europe for prescription pharmaceuticals and pharmaceuticals administrated in hospitals, respectively. The per capita average is approximately SEK 4,720. Total sales value per capita is highest in Switzerland (approximately SEK 8,100 per capita), followed by Austria (approximately SEK 6,900 per capita). Sweden has the twelfth highest sales of all countries, with approximately SEK 4,500 per capita.

In terms of total sales value per capita, our Nordic neighbouring countries, Denmark, Norway, and Finland, have slightly higher costs than Sweden. See Figure 3 below.

Figure 3. Sales value in SEK AIP per capita that is managed in hospitals and as prescription pharmaceuticals, by country



Source: IQVIA and TLV analysis.
Note: Data regards March 2022, 12-month rolling average, rounded to even hundreds. Greece has been excluded as there is no available information on pharmaceuticals administrated in hospitals.

Figure 3 includes both pharmaceuticals dispensed in retail pharmacies and in hospitals. The remainder of the report includes only prescription pharmaceuticals dispensed in retail pharmacies. The main reason for this is that TLV sets prices for prescription pharmaceuticals, while pharmaceuticals administrated in hospitals are procured within the healthcare system.

3 Price comparisons

This chapter presents the results of the comparison of Sweden's pharmaceutical prices in relation to other comparison countries. The results are presented in five sections:

- *Prices over a pharmaceutical's life cycle*
- *Pharmaceuticals without generic competition*
- *Pharmaceuticals with generic competition*
- *Price comparison – focus on selected pharmaceutical classes*
- *Bilateral average – price comparison given other countries' volumes*

The first section analyses Swedish pharmaceutical prices in relation to the average for all countries over the life cycle of a pharmaceutical, i.e. based on the number of years after marketing authorisation.

In the next section, pharmaceuticals are divided into two different segments based on the competitive situation, defined as whether a pharmaceutical has generic competition (is part of the Swedish PV system) or not. The division is based on the fact that the price dynamics and the market situation differ greatly between pharmaceuticals with and without generic competition.

Prices are then analysed as in previous sections for the Nordic countries, but with a focus on selected pharmaceutical classes relating to asthma/COPD products (inhalers), insulin and ADHD medicines. The chapter concludes with a section that implements an alternative methodology to address differences in country product baskets in the price comparison – *Bilateral average*. The method takes into account all countries' use when calculating the price index (see *Appendix 2: Methodology and data)*.

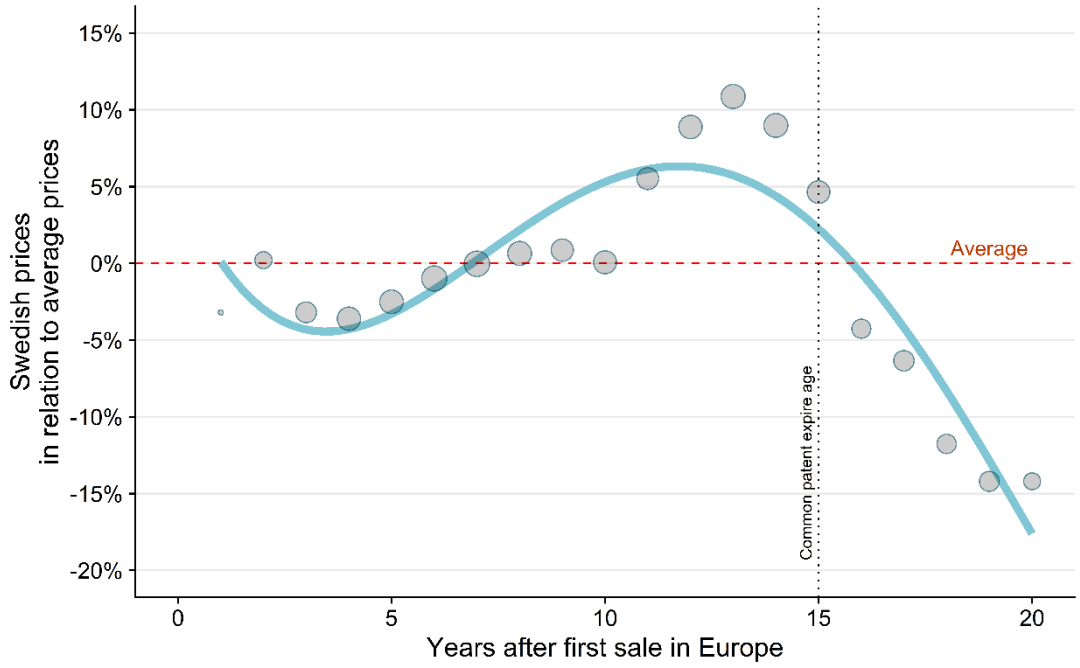
3.1 Prices over a pharmaceutical's life cycle

The following section compares prices in Sweden with the averages of other countries over the life cycle of a pharmaceutical – for all pharmaceuticals sold in Sweden during the period 2014–2022. Prices of pharmaceuticals can change significantly over time based on the competitive situation and different types of interventions such as reassessments. This section presents how Swedish pharmaceutical prices change compared to the European average over the life cycle of a pharmaceutical for the given period. The same analysis with a limited time period, 2019–2022, is included as a sensitivity analysis in the section, while providing a more time-related picture with the consequence that fewer observations are found at each individual pharmaceutical age. Additionally, this analysis is also performed with price data limited to 2022 in *Appendix 1* under Section *1.8*. For further sensitivity analyses, please see Appendix 1 under Sections *1.6* and *1.7*, where we exclude individual pharmaceutical classes and comparison countries to map their impact on outcomes and identify groups with the greatest impact on outcomes in different parts of the life cycle.

Figure 4 covers the entire period 2014–2022, which means that a single pharmaceutical may be included in several age categories (counted as years after marketing authorisation). The sales volume in 2014–2022, calculated as total AIP per year after marketing authorisation, is indicated by the size of the circles in the figure, where a larger circumference means larger sales. The light blue curve corresponds to a model adaptation of the circles to show the trend over the life cycle.

Measured as list prices, Sweden has, on average, lower prices than the average of the included countries during the first five years after marketing authorisation. Swedish pharmaceutical prices remain around the European average during the subsequent five years, and then rise above the EU average between year 10 and year 15. Finally, after 15 years on the market, which roughly corresponds to the date a pharmaceutical's patent expires, Sweden's pharmaceutical prices, on average, fall below the European average. After 20 years on the market, the average price of a pharmaceutical in Sweden is 15 percent lower than the average price in the included countries.

Figure 4. Sweden's relative pharmaceutical prices in 2014–2022 compared to the average price of the 20 European countries included in the report. Comparison is by year after marketing authorisation.



Source: IQVIA and TLV analysis.
Note 1: The red dashed line shows the average prices for the 20 European countries. The position of the circles shows the actual deviation from the average prices, and their size indicates the sales value in Sweden for pharmaceuticals of that age. The light blue line is a polynomial regression (fourth degree polynomial) adapted to the data points. Sales data for the period 2014–2022.
Note 2: The figure should be interpreted as Sweden's average relative price per pharmaceutical age for all years 2014–2022. Thus, it only indicates what Sweden's relative price level is for the entire period.

The fact that the light blue curve is above the average should not be interpreted as an indication that Swedish pharmaceutical prices are increasing in this age range. Rather, the explanation is that prices for these pharmaceuticals are falling in other

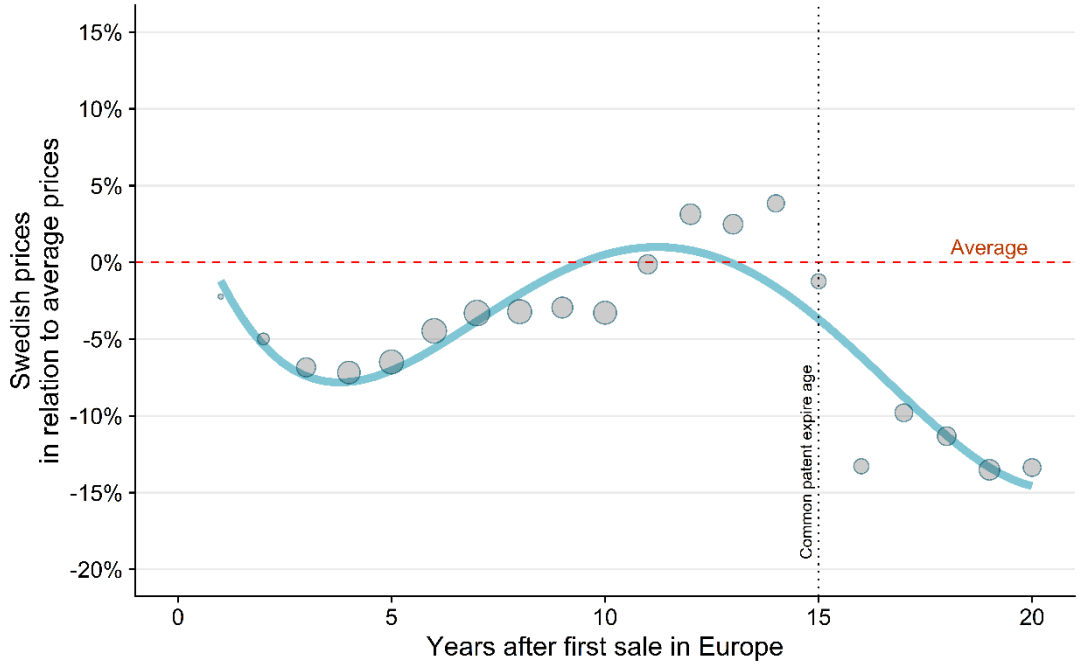
countries while Swedish prices remain at the original price level (see Figure 8, where price dynamics for each country are visualised separately). For pharmaceuticals older than 15 years, Swedish pharmaceutical prices fall below the average. One explanation for this is that the 15-year rule reduces the price by 7.5 percent for pharmaceuticals (substance and dosage form) that have been authorised for 15 years.[11]

More important from a price perspective, however, is that patents expire after about 15 years on the market, which for many pharmaceuticals means that generic competition arises, leading in most cases to lower prices. Sweden applies the product-of-the-month system (PV system) to pharmaceuticals with generic competition, which means that there is a switch at pharmacies to the available pharmaceutical with the lowest price in the respective substitution group during the month in question (provided that the patient, prescriber or pharmacist does not object to the switch).[12] As evident from the size of the circles in Figure 4, pharmaceuticals between 5 and 15 years old are a large group in terms of sales, accounting for 40 percent of prescription pharmaceutical costs in Sweden during the period 2014–2022.[13]

Figure 5 illustrates how a shorter period with data for the last 4 years (2019–2022) affects the analysis. A shorter time period focusing on the years closest in time has the advantage that the list prices in the analysis are centred on the most recent ones, but the disadvantage that fewer pharmaceuticals are included and that a pharmaceutical can be observed at fewer ages over the life cycle. Pharmaceuticals that have been on the market for less than 5 years account for around 16 percent of total pharmaceutical sales in Sweden, which is slightly lower than the longer period (Figure 4), where the corresponding figure is 17 percent.

[11] TLV (2022) Prissänkning enligt 15-årsregeln
[12] TLV (2022) Periodens varor
[13] Pharmaceuticals less than 5 years old account for 17 percent of pharmaceutical costs and those older than 15 years account for 42 percent.

Figure 5. Sweden's relative pharmaceutical prices in 2019–2022 compared to the average price of the 20 European countries included in the report. Comparison is by year after marketing authorisation.



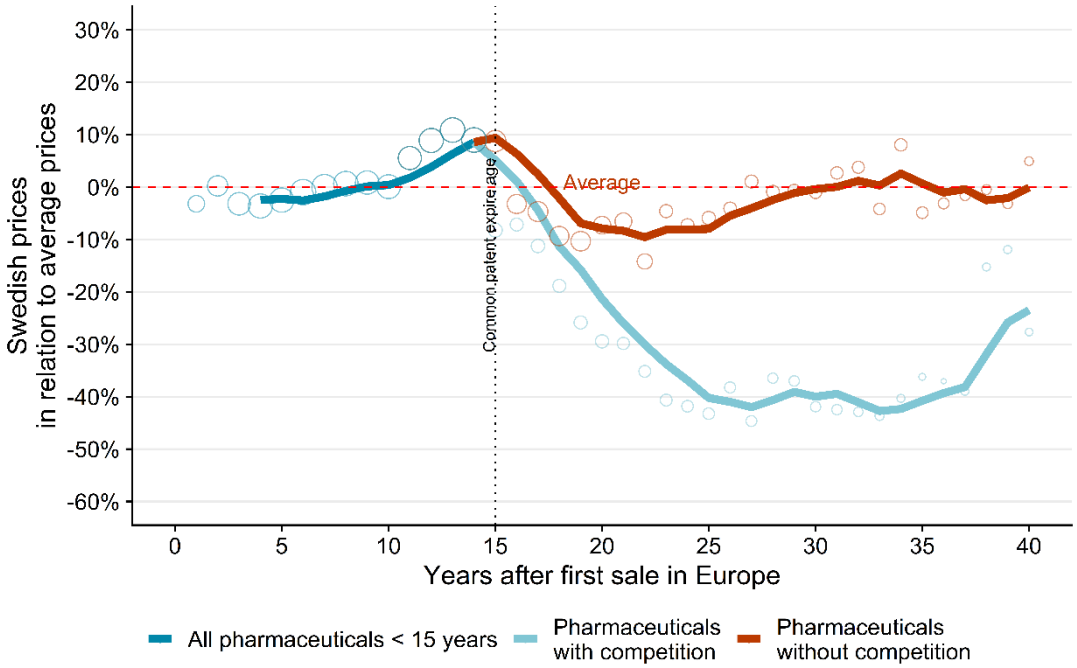
Source: IQVIA and TLV analysis.
Note 1: The red dashed line shows the average prices for the 20 European countries. The position of the circles shows the actual deviation from the average prices, and their size indicates the sales value in Sweden for pharmaceuticals of that age. The light blue curve is a polynomial regression (fourth degree polynomial) adapted to the data points. Sales data, 2019–2022.
Note 2: The figure should be interpreted as Sweden's average relative price per pharmaceutical age for all years 2019–2022. Thus, it only indicates what Sweden's relative price level is for the entire period.

The profile of the curve for the shorter period is similar to that of the period 2014–2022 but it is offset downwards, i.e. Sweden's relative price level is lower in the period 2019–2022. This is largely due to the exchange rate but also to the fact that top sellers in the TNF segment have lost patent protection and become relatively cheaper in Sweden (see Figure 33 in Appendix 1, where the pharmaceutical class TNF-alpha inhibitors is excluded from the life cycle analysis).

The above analysis illustrates that the choice of time period influences the outcome of the analysis, although the general conclusion remains the same – Sweden's relative pharmaceutical prices are highest compared to the European average in the 5 to 15 year age range.

In Figure 6, pharmaceuticals older than 15 years are divided into pharmaceuticals with and without generic competition based on the period 2014–2022.

Figure 6. Sweden's relative pharmaceutical prices in 2014–2022 compared to the average price of the 20 European countries included in the report. Comparison is by year after marketing authorisation.

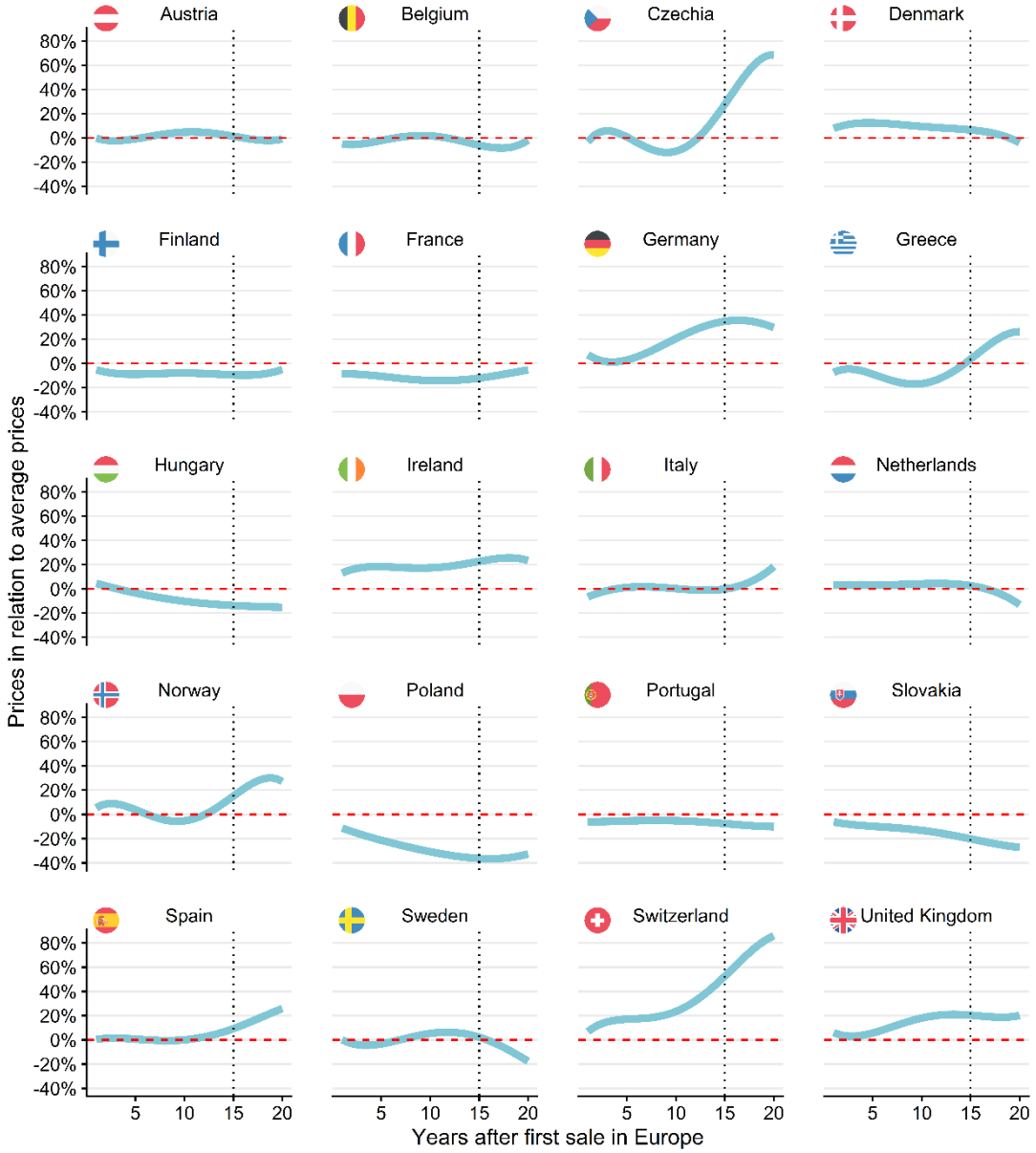


Source: IQVIA and TLV analysis.
Note 1: The red dashed line shows the average prices for the 20 European countries. The position of the circles shows the actual deviation from the average prices, and their size indicates the sales value in Sweden for pharmaceuticals of that age. The dark blue, light blue and red curves are polynomial regressions (fourth degree polynomials) adapted to the data points. Sales data, 2014–2022.
Note 2: The figure should be interpreted as Sweden's average relative price per pharmaceutical age for all years 2014–2022. Thus, it only indicates what Sweden's relative price level is for the entire period.

Figure 6 shows a large difference in relative prices between pharmaceuticals with and without generic competition. For pharmaceuticals that have been on the market for 20–25 years, the prices are below average for pharmaceuticals both with and without generic competition. For pharmaceuticals with generic competition that have been on the market for 25–35 years, Swedish prices are much lower than the average (approximately 40 percent). The generic competition segment comprises pharmaceuticals included in the Swedish PV system, which means that the product (within a group of substitutable pharmaceuticals with comparable pack sizes) that is available and has the lowest price becomes the product-of-the-month and thus receives almost all sales that month. This system results in significant price pressure within the segment.

Figure 7 shows prices over the life cycle relative to the average for the 20 European countries, for each country in the study. The figure shows that the different price and subsidy systems among the countries compared lead to large differences in the way relative price levels evolve over time.

Figure 7. All countries' relative list prices in 2014–2022 compared to the average price for the 20 European countries in the report, by year after marketing authorisation



Source: IQVIA and TLV analysis
Note 1: Norway and Czechia should be interpreted with caution for pharmaceuticals older than 15 years. This is because the structure of their subsidy system means that list prices and transaction prices differ significantly. The observations in this figure only show list prices.
Note 2: The red dashed line shows the average prices for the 20 European countries. The light blue curve in the figures is a polynomial regression (fourth degree polynomial), i.e. a model adapted to the data points. Sales data for prescription pharmaceuticals, 2014–2022.

In Sweden, decisions on subsidies are made based on whether the cost of a pharmaceutical is considered reasonable in relation to the benefit of the treatment it provides, referred to as value-based pricing.[14] The regions receive compensation from the central government for the pharmaceutical costs, based on an annual forecast of pharmaceutical sales published by the National Board of Health and Welfare.[15] The forecast is based on expected use in the coming years and there is thus no strict budget at the national level for prescription pharmaceuticals in

[14] TLV (2022) Utveckling värdebaserad prissättning
[15] National Board of Health and Welfare (2022) Läkemedelsförsäljning i Sverige – analys och prognos

Sweden. The management of pharmaceuticals from a budgetary perspective varies between regions.

Several countries have regulatory frameworks that deal with pharmaceutical prices once a pharmaceutical has been on the market for a few years. One example is Finland, which has time-limited subsidy decisions that are valid for a maximum of three years for new active substances and up to five years for other pharmaceuticals, after which companies must re-apply for reimbursement.[16] Finland has lower prices than Sweden for pharmaceuticals between 5 and 15 years old. Another example is France, which regularly reassesses price and subsidy status after five years.[17] France also applies volume agreements upon market entry, which are then converted into list price reductions after a number of years based on framework agreements with manufacturers. Compared with Sweden, France has lower prices on pharmaceuticals that have been on the market between 5 and 15 years.

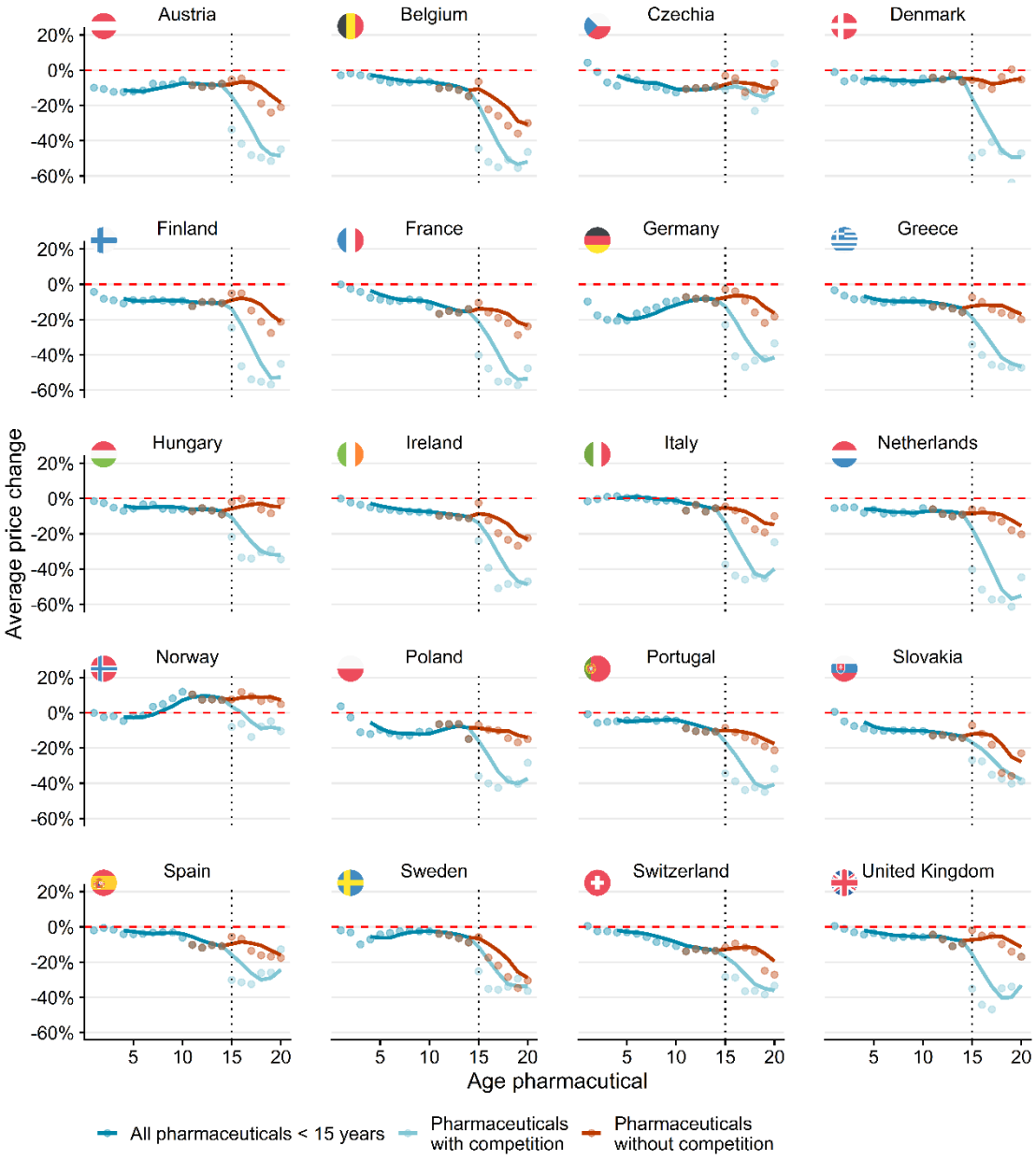
Another country that has a system different from Sweden's is Norway, where reference prices from 9 other countries, including Sweden, are used for pricing pharmaceuticals. Prices are continuously adjusted at regular intervals based on the evolution of the exchange rate, which has contributed to higher pharmaceutical costs in the country over time. The intervals differ based on the size of sales, with an annual revision of prices for the best-selling pharmaceuticals.[18] Such price adjustments are not made under the Swedish model and can be seen as a contributing factor to Sweden's low pharmaceutical prices from an international perspective.

Sweden's low prices, relative to the average, for pharmaceuticals over 15 years old can largely be explained by the PV system, which promotes price competition.[19] A similar pattern, with falling relative price levels after 15 years, can be seen in e.g. the Netherlands and Denmark, which like Sweden apply a generic substitution system for off-patent pharmaceuticals.

Figure 8 illustrates how prices evolve on average over the life cycle of a pharmaceutical product for each country in the study. Unlike Figure 7, which compared price levels between countries, this figure focuses on the dynamics of price changes within each country. As before, the price information for the pharmaceuticals cover the period 2014–2022, meaning that the initial price we identify for each drug and country are situated in different parts of the life cycle. Thus, older pharmaceuticals will have an index price taken from a later point in their life cycle. This analysis only includes pharmaceuticals for which a price can be observed before pharmaceutical age 15. It includes top-selling pharmaceuticals in Europe and products that are included in the WAIT study, regardless of whether Sweden had sales of these products. The average price change since the first observed price is weighted based on the sales volume of the respective pharmaceutical, country, and year. This means that changes over time can be associated with changes in price, the proportion of sales of the pharmaceutical versus other pharmaceuticals in a given period and the product basket.

[16] FIIMEA and KELA, SLT FSM 2015 p. 93
[17] HST (2015) France. Health system review
[18] PPRI (2018) PPRI Pharma Profile – Norway 2018
[19] TLV (2022) Prissänkning enligt 15-årsregeln

Figure 8. Average domestic price development of list prices for all countries 2014–2022 compared to first observed price, by year after marketing authorisation



Source: IQVIA and TLV analysis.
Note 1: Only pharmaceuticals for which prices and volumes can be observed at pharmaceutical age 15 or earlier are included. As all countries are analysed separately, all pharmaceuticals are included for each country, regardless of the Swedish product basket.
Note 2: Combinations of pharmaceuticals and pharmaceutical age where the price change exceeds 200 percent are excluded from the analysis.

Most countries show a clear reduction in prices after pharmaceutical age 15. Differences between countries can mainly be seen in the magnitude of the price changes and the period prior to the pharmaceutical age 15. The Netherlands shows the largest reduction in prices after the age of 15, with a reduction of around 60 percent for pharmaceuticals with generic competition (as defined by Sweden). This can be compared to Sweden, where we see an average price reduction of about 40 percent.

Before pharmaceuticals reach the age of 15, differences in price dynamics can be seen between countries. Germany shows a clear reduction in initial prices between pharmaceutical ages 1-5, where the average price change is at most around 20 percent below the initial price. The fact that we then see the curve rise slightly do not necessarily mean that prices are increasing, but may be due to the fact that the product basket in our data varies over the life cycle. Similar trends as in Germany can also be seen in countries such as France, Switzerland, Finland and Slovakia. In Figure 7, which shows the relative price change compared to the European average over the life cycle of pharmaceuticals, Germany is one of the countries that is highest above the European average (3rd highest at pharmaceutical age 15). This means that Germany's prices at entry are relatively high, but that price dynamics over time follow the trend of falling prices.

Norway shows prices starting to increase from pharmaceutical age 7 onwards, averaging around 10 percent above initial prices. The dynamics illustrated in Figure 8 capture, among other things, the price adjustments to pharmaceutical prices that Norway regularly makes to deal with exchange rate changes. [20] Norwegian prices are on average stable for the no generic competition segment after pharmaceutical age 15, while a decrease can be seen for those with generic competition over the same period, but with lower price decreases than for e.g. Sweden.

In Sweden, a clear decrease in prices after pharmaceutical age 15 can be observed for pharmaceuticals both with and without generic competition. In Sweden, rule-based price reductions of 7.5 percent are made for pharmaceuticals that have been on the market for 15 years but where no or limited generic competition has arisen. For those pharmaceuticals where generic competition arises, the Swedish PV system creates incentives for price reductions among the competing companies within a substitution group.

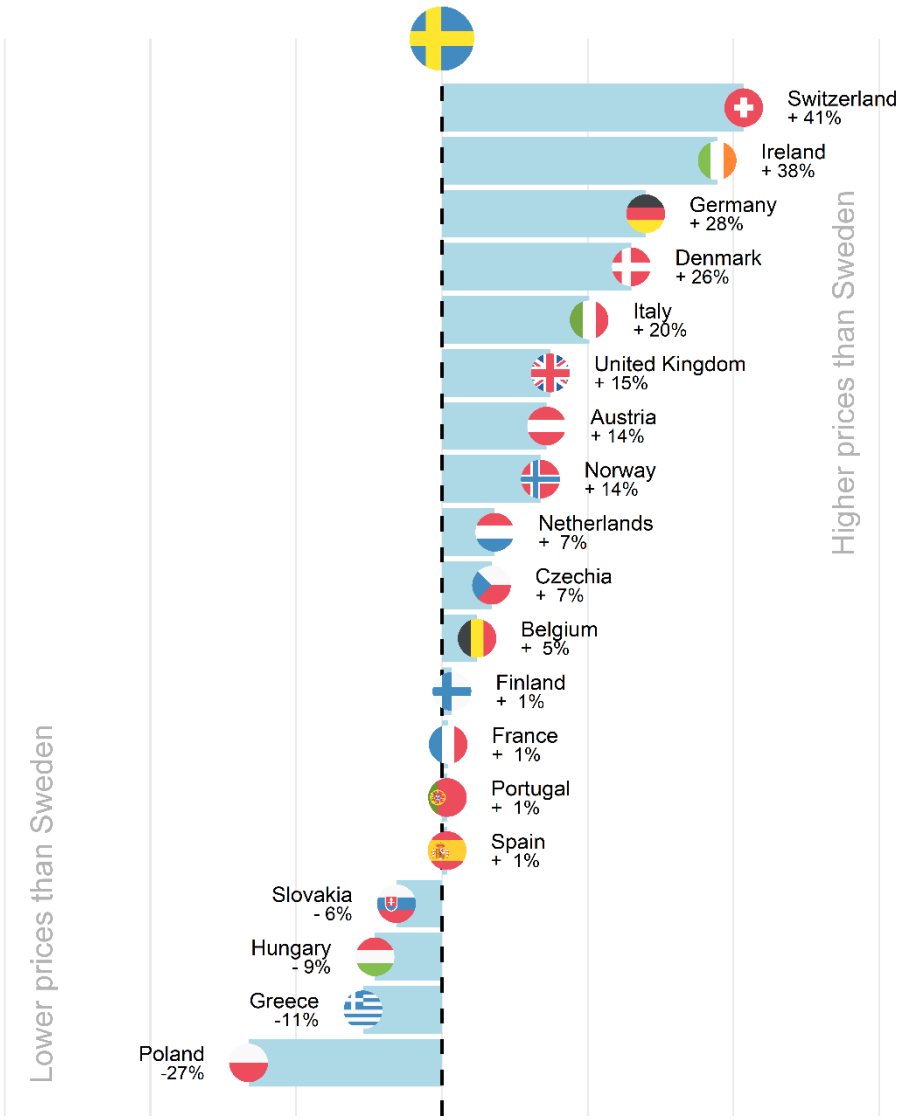
3.2 Pharmaceuticals without generic competition

The segment of pharmaceuticals without generic competition consists mainly of newer pharmaceuticals that still have active patents, as well as older pharmaceuticals that lack generic competition. The latter is the case, for example, for those pharmaceuticals that the Swedish Medical Products Agency has deemed to be non-substitutable.

Figure 9 presents the bilateral price comparison weighted by Swedish sales volumes, including only drugs available in both Sweden and the comparison country. The selection of drugs available in both countries may vary among the countries included, affecting the interpretation of the comparison. Therefore, the drugs included in the comparison between Sweden and Norway may differ from those in the comparison between Sweden and Spain, making it inappropriate to use Figure 9 to compare prices between Norway and Spain.

[20] PPRI (2018) PPRI Pharma Profile – Norway 2018

Figure 9. Bilateral price comparison for pharmaceuticals without generic competition, 2022



Source: IQVIA and TLV analysis.
Note: Prices during Q1 2022. Volume regards March 2022, 12-month rolling average.

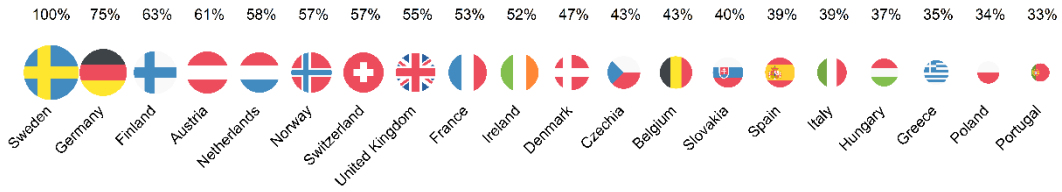
Figure 9 shows that a majority of the countries in the survey have higher list prices for pharmaceuticals without generic competition than Sweden. The figure shows that Sweden's costs for matching pharmaceuticals without generic competition sold in both Sweden and Switzerland would have been 41 percent higher if they had been purchased at Swiss prices instead of Swedish prices. Similarly, the cost of pharmaceuticals without generic competition sold in both Poland and Sweden would have been 27 percent lower if they had been purchased at Polish prices compared to Swedish prices.

Sweden has higher prices than four of the countries, and is at comparable price levels to Finland, France, Portugal and Spain. The countries with lower prices than Sweden generally have a low matching rate to Swedish use, which means that the results should be interpreted with caution. Countries with higher prices than Sweden generally have a higher matching rate. The term “matching rate” and its relevance to the analysis is described in the next section.

3.2.1 Matching rate

The matching rate illustrates the proportion of prescription pharmaceuticals sold at pharmacies in Sweden that are also available in other countries with the same sales criteria (see Figure 10). Pharmaceuticals administrated at hospitals (hospital pharmaceuticals) are not included in the analysis. Pharmaceuticals with significantly fewer sales per capita than in Sweden are also excluded from the bilateral comparison. See Appendix 1 for more information.

Figure 10. Swedish matching rate for pharmaceuticals without generic competition



Source: IQVIA and TLV analysis.

In Sweden, there are a total of 1,312 pharmaceuticals in the sample for this segment with sales in Q1 2022. These pharmaceuticals form the basis of the price comparison with the other countries. Sales of pharmaceuticals in other countries that do not match those found in Sweden have therefore been excluded (even if the substance itself is available in other countries). The number of pharmaceuticals available in Sweden (counted by substance, form and strength) is therefore the maximum number of pharmaceuticals included from other countries.

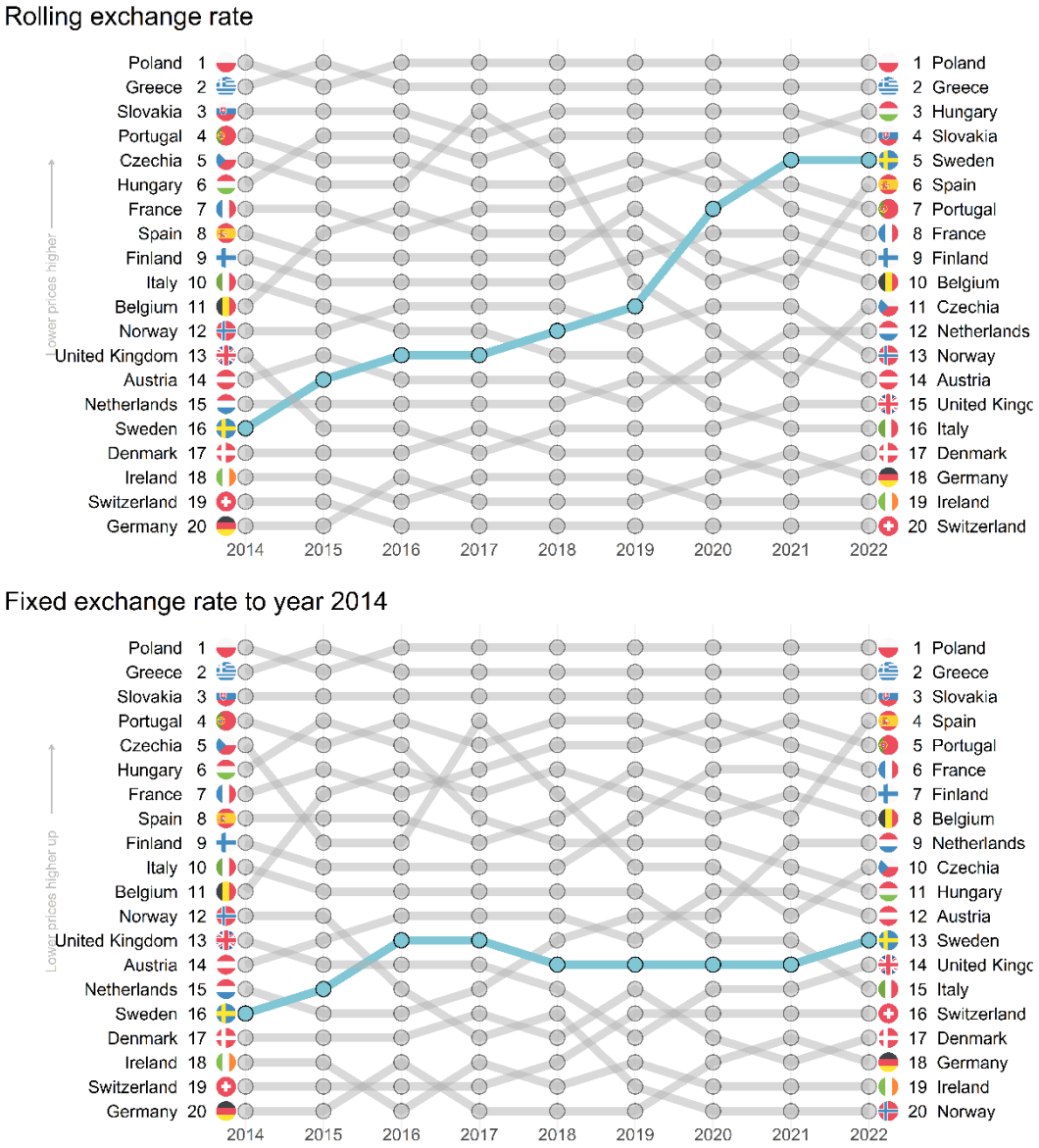
For pharmaceuticals without generic competition, the highest matching rate is for Germany, where 75 percent of the pharmaceuticals used in Sweden are also used. This is followed by Finland, Austria, the Netherlands, Norway, Switzerland and the UK, with a matching rate between 55 and 63 percent. The lowest matching rate is for countries such as Portugal, Poland, Greece, Hungary, Italy and Spain, which all have a matching rate below 40 percent. Thus, a comparison between Germany and Sweden is based on 75 percent of the pharmaceuticals available in Sweden and a comparison with Portugal is based on only 33 percent. Bilateral price comparisons can therefore only compare the respective country with Sweden, not other countries with each other. Differences in the matching rate may, for example, be due to the fact that some countries use different pharmaceuticals than in Sweden, or that pharmaceuticals prescribed in Sweden are administrated in hospitals in other countries and vice versa.

Differences in matching rates between countries are important to consider when looking at differences in a bilateral price comparison. A high matching rate and a pharmaceutical use similar to that in Sweden makes the price comparison more robust. Comparisons with countries that have a very low matching rate will be more difficult to generalise, as the comparison is only relevant for the small number of products that are common.

3.2.2 Historical development

In recent years, pharmaceutical prices in Sweden have fallen in relation to other countries in the comparison. This is primarily explained by the fact that the Swedish krona has declined in value compared to the euro. This also means that the Swedish pricing system is robust even in times when the exchange rate weakens.

Figure 11. Development of the bilateral price comparison over time, 2014–2022. Three-year rolling average exchange rate and fixed three-year average exchange rate from 2014. Pharmaceuticals without generic competition



Source: IQVIA and TLV analysis.
Note 1: Rank 1 means that the country has the lowest prices. Three-year rolling average exchange rate (first figure) and fixed three-year average exchange rate from 2014 (second figure), by year.
Note 2: As the bilateral comparison uses Sweden's volume weights, interpretations between countries other than Sweden should not be made.

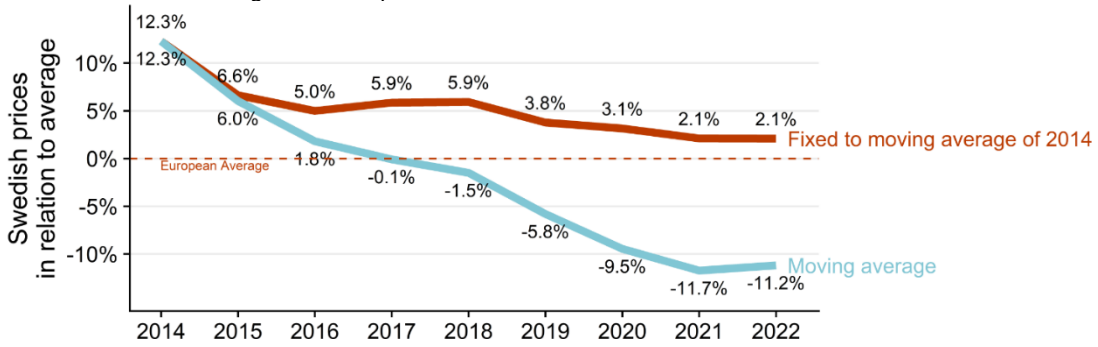
The top graph of Figure 11 shows how Sweden's prices have changed relative to other countries between 2014 and 2022, going from having the sixteenth to the fifth lowest prices over the period. The main explanation for this change has been the exchange rate. In the bottom part of the figure, where the exchange rate is kept

constant, Sweden has moved from sixteenth to thirteenth place. Sweden's prices fell in relation to other countries between 2015 and 2016, as TLV conducted many reassessments during this period.

In many cases, the percentage difference in price level between the countries is small. Sweden's position in the top graph of Figure 11 may therefore be moved down, i.e. Swedish relative prices will increase, if the Swedish krona strengthens. A general observation is that the countries whose currency is not tied to the euro have a greater variation in position than other countries.

Figure 12 shows the percentage deviation between prices in Sweden and the average prices in other countries between 2014 and 2022. As in Figure 11, the analysis includes a line using a rolling exchange rate and a line using the 2014 exchange rate. This analysis shows that Sweden's prices relative to the rest of Europe have fallen since 2014, regardless of the type of exchange rate adjustment used. To get a better picture of the development, it is also interesting to look at the magnitude of this change.

Figure 12. Sweden's relative prices compared to the average per year, calculated as a cross-section. Three-year rolling average exchange rate and fixed three-year average exchange rate from 2014. Pharmaceuticals without generic competition



Source: IQVIA and TLV analysis.
Note: Calculation based on cross-section. Three-year rolling average exchange rate (light blue) and fixed three-year average exchange rate from 2014 (red), by year.

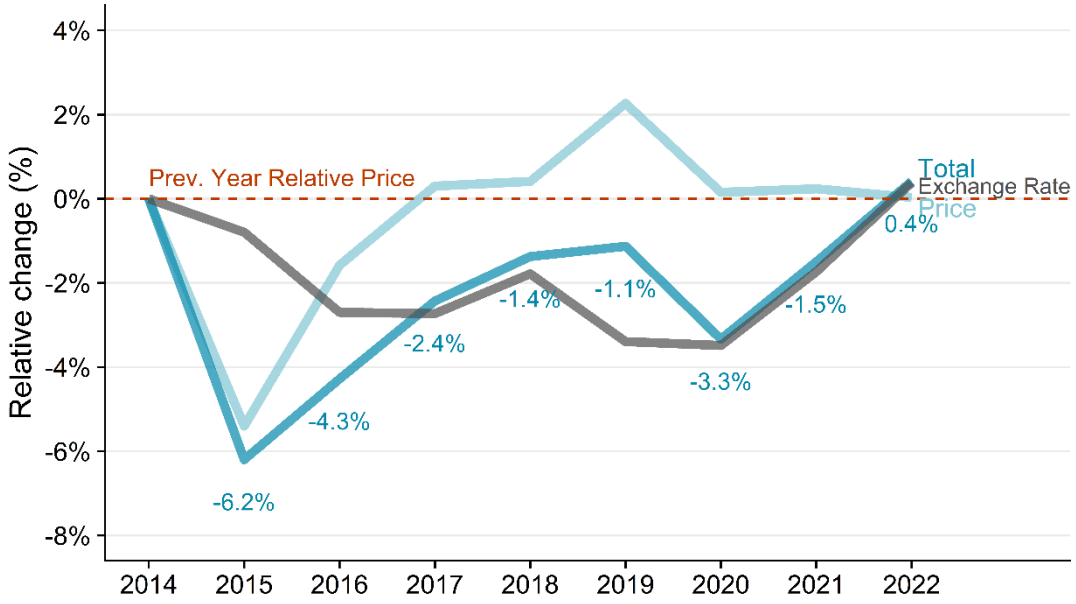
Figure 12 shows that Sweden's prices in 2014 were 12.3 percent higher than the average for all countries. Using a rolling exchange rate, we see that Sweden's relative prices gradually decreased by around twenty percentage points up to Q1 2021, when Sweden's prices were 11.7 percent lower than the average. In Q1 2022, the downward trend came to a halt, with relative prices remaining 11.2 percent below the average. Using a fixed exchange rate, Sweden's relative prices fell by around ten percentage points up to Q1 2021, and then stabilised at a relative price of 2.1 percent above the average. The change over time is largely driven by the exchange rate change.[21] However, from 2014 to 2016, the relative price decrease was mainly driven by reassessments and the introduction of rule-based price reductions for pharmaceuticals 15 years and older. This change can be seen in Figure 13. As previously mentioned, Sweden's relative prices would likely rise if the Swedish krona regained its value. The following section provides a more detailed description of the reasons behind this price development.

[21] A version of the figure with fixed exchange rate is found in Section 1.1 of Appendix 1.

3.2.3 Price and currency effects

The relative price development of pharmaceuticals in Sweden compared to other European countries is influenced by several factors. Figure 13 shows a breakdown of how much of the change in the relative price level between each year is driven by changes in the exchange rate and by changes in the price of pharmaceuticals.

Figure 13. Relative price's change effects broken down by price and currency changes. Pharmaceuticals without generic competition weighted by 2014 use in Sweden.



Source: IQVIA and TLV analysis.

The *currency* category includes the part of Sweden's relative price level that is entirely driven by the falling Swedish krona. The second category, *price*, is influenced by both changes in pharmaceutical prices in the rest of Europe and changes in Swedish pharmaceutical prices. The negative price change effect in Figure 13 may thus be due to falling prices in Sweden *or* rising prices in other countries. The 2015 price reduction effect is largely due to price reductions as a result of reassessments during this period in Sweden and the introduction of the 15-year rule[22]. Reassessments have also been carried out since 2016, but they have resulted in limited reductions in list prices. Instead, Sweden has since 2016 primarily focused on managed entry agreements on repayments from companies to regions, resulting in reduced costs that are not reflected in reduced list prices.[23] Managed entry agreements do not affect list prices. Please note that cost changes as a result of managed entry agreements are not included in Figure 13 (this also applies to other analyses in the report).

In order to distinguish the price effect from the cost changes resulting from different pharmaceuticals being used in varying extent between years, the analysis includes only those pharmaceuticals that had use in all years between 2014 and 2022. For the same reason, use is weighted according to how these pharmaceuticals

[22] This work was done in the context of the previous savings plan 2014–2017, as set out in the 2014 budget proposal.
[23] TLV (2021) Prognos av besparingar från sidoöverenskommelser helåret 2021

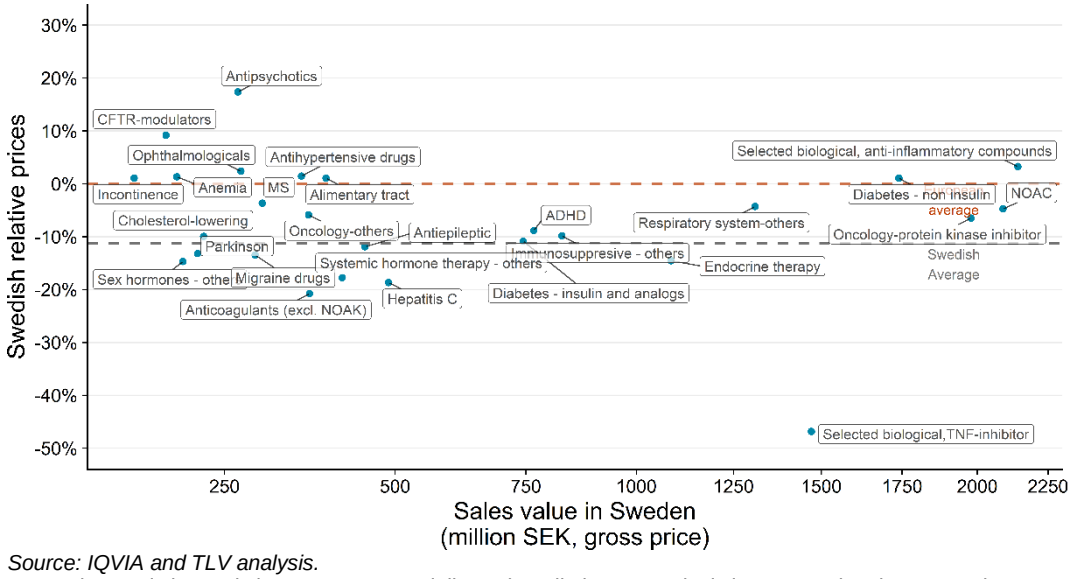
were used in 2014. As in previous analyses based on cross-sections, the price category is weighted according to how much use a particular pharmaceutical had in Sweden. Price changes for pharmaceuticals with high use thus have a greater effect than an equally large price change for a pharmaceutical with lower use.

The sum of the two components, price and currency, together make up the *total relative price change*. A total effect that is negative and is below the red dashed line means that Swedish relative prices are *lower* than in the previous year. Q1 2022 is the first time during the period under review that the total relative price change has been above zero (0.4 percent). This is mainly driven by the Swedish exchange rate, where the 3-year rolling average exchange rate shows a slight increase relative to other currencies compared to the average of the previous year. A more detailed description of the calculations and methodology behind Figure 13 is presented in *Appendix 2*.

3.2.4 Pharmaceutical classes

There is a spread in Sweden's relative prices among the pharmaceuticals included in the analyses. Figure 14 shows Sweden's relative prices and total sales in Sweden in 2022 based on the total AIP,[24] divided into different pharmaceutical classes[25]. Only the classes with the highest sales are shown in the figures below.

Figure 14. Swedish prices for pharmaceutical classes compared to European average AIP, in relation to total AIP, 2022. Pharmaceuticals without generic competition



Source: IQVIA and TLV analysis.
Note: The x-axis intervals increase exponentially so that all pharmaceutical classes can be shown together. Pharmaceutical classes with AIP sales of less than SEK 150 million have been excluded for the same reason.

The pharmaceuticals included in this analysis are not included in the PV system as they still have active patents, or the patent term has expired but no generic competition has arisen.

[24] The sales total is calculated as the price range in Q1 2022 multiplied by the rolling 12-month volume of the respective pharmaceutical in Q1 2022.
[25] For more information on pharmaceutical classes, see *Appendix 2*, Section *2.8 Pharmaceutical classes*.

The pharmaceutical classes with the highest sales in Sweden are “Selected biological, anti-inflammatory compounds”, “NOACs”, “Oncology – protein kinase inhibitors”, “Diabetes – non insulin”, “Haematology – others” and finally “Selected biological, TNF inhibitors”. Of these top-selling pharmaceutical classes, the average price for “Diabetes – non insulin” and “Selected biological, anti-inflammatory compounds” is just above the European average, while the others are below.

Within the immunosuppressive pharmaceutical classes, Figure 14 shows that “Selected biological, TNF inhibitors” have high sales in Sweden with a relative price level well below the European average. There were managed entry agreements within this pharmaceutical class up until October 2021, but these were not renewed. List prices have since fallen, and Sweden's relative prices in this year's comparison of list prices have thus reached lower levels than in previous years' comparisons. As other countries may also have managed entry agreements, it is not possible to make a statement on the actual price level in Sweden compared to other countries.

One perspective not captured in Figure 14 is how Sweden's relative prices have changed over time for the different pharmaceutical classes. This is illustrated in Figure 15. Each colour represents a year, the size of the dots shows the proportion of sales value the class accounted for, and the position of the dot relative to the grey dashed line shows how far above or below the average prices of the pharmaceutical class are compared to the European average. The outer circle categorises the pharmaceutical classes based on their relative prices in 2022. The green part contains the pharmaceutical classes that are below average (more than 2 percent), the grey one shows those that are around average (between 2 percent below and 2 percent above) and the red one shows those that are above average (more than 2 percent). The pharmaceutical classes are sorted by the relative prices for 2022.

Figure 15. Swedish prices for pharmaceutical classes compared to European average AIP, 2014–2022. Pharmaceuticals without generic competition

Source: IQVIA and TLV analysis.
Note 1: Green: Prices below the European average 2022 (more than two percent below); Grey: Prices around the average 2022 (between 2 percent below and 2 percent above) and Red: Prices above the European average 2022 (more than 2 percent above).
Note 2: [1] indicates that managed entry agreements existed for the pharmaceutical class in 2022. [2] indicates that managed entry agreements existed in other years for the pharmaceutical class.

Based on the pharmaceutical classes with the highest sales in 2022, “Selected biological, anti-inflammatory compounds” and “Diabetes – non insulin” have relatively low fluctuation over time. For the “Haematology – others” class, the relative price was about 10 percent above average in 2014, but this period was also associated with lower sales compared to subsequent years. “Oncology – protein kinase inhibitors” shows a gradual decline in relative price over time, from around 10 percent above the average in 2014 to around 8 percent below the average in 2022. The “Selected biological, TNF inhibitors” class shows one of the largest changes over time, with relative prices falling from around 15 percent above the average in 2014 to around 45 percent below the average in 2022. A contributing factor is that biosimilars are now also available on the market at a significantly lower price than original pharmaceuticals.

Generally speaking, relative prices have risen slightly. This can be seen from the Swedish average, which is 11.2 percent below the European average, compared to 2021 levels, where the Swedish average was around 11.7 percent below the European average. Measured in Swedish kronor, list prices do not change much until generic competition arises in the PV system, or when competition is stimulated by TLV performing reassessments. Without intervention or regulatory price reductions, spontaneous price competition between pharmaceuticals rarely occurs in the Swedish market.

Most of the groups of pharmaceutical classes shown in Figure 15 have or have had active managed entry agreements in Sweden (labelled [1, 2] in the figure). For these classes, this means in effect that the price levels shown in Figure 14 and Figure 15 are lower for society. As other countries may also have managed entry agreements, it is not possible to make a statement on the actual price level in Sweden compared to other countries for these classes, even if the list prices are lower.

3.3 Pharmaceuticals with generic competition

The report defines pharmaceuticals with generic competition as those that are available in the Swedish PV system, i.e. pharmaceuticals that the Swedish Medical Products Agency has classified as substitutable and where generic competition has arisen. These are older pharmaceuticals for which the patents are no longer valid, which in most cases occurs about 15 years after market introduction (patent expiry). However, there are many pharmaceuticals over 15 years old that do not have generic competition, and there are also pharmaceuticals that are not classified as generically substitutable by the Swedish Medical Products Agency, such as biosimilars and epilepsy medicines.

In the Swedish PV system, substitutable pharmaceuticals are divided into substitution groups based on substance, dosage form, strength and pack size. The pack (per NPL pack ID) with the lowest price within a pack size group and whose company has confirmed for each month that the pack can be supplied to the Swedish market then becomes the product-of-the-month. Since the pack with the lowest price becomes the product-of-the-month and thus accounts for most of the sales in the pack size group during the month in question, price competition between companies is created.

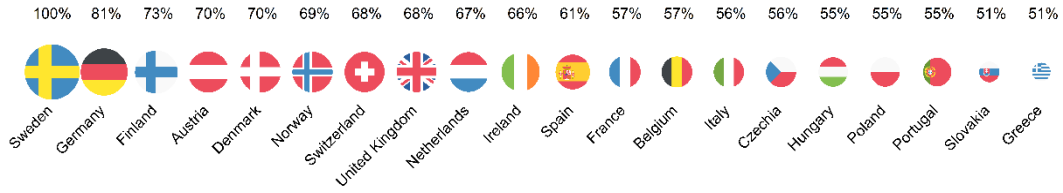
Furthermore, Sweden has a system of price ceilings in the segment of pharmaceuticals with generic competition, whereby when the unit price in a substitution group has fallen below 30 percent of the original price, a ceiling price is set at 35 percent of the highest price in the group when generic competition arose.[26] Ceiling prices mean that the price within a group can be freely increased up to the ceiling price level. Sweden's pricing model creates scope for price dynamics, as can be seen, for example, in the fact that pharmaceuticals with and without generic competition have been affected differently by exchange rate fluctuations.

[26] TLV (2022) Takpriser

3.3.1 Matching rate

In Sweden, there are a total of 637 pharmaceuticals in the sample for pharmaceuticals with generic competition that had sales in Q1 2022. These pharmaceuticals form the basis of the bilateral price comparison that is made with the included comparison countries. For pharmaceuticals with generic competition, the matching rate is on average significantly higher than for pharmaceuticals without generic competition. Figure 16 also shows that matching rates differ widely between countries. Germany has the highest match rate with Sweden at 81 percent, while Greece and Slovakia have the lowest match rate with Sweden at 51 percent for 2022. The matching rate for all countries is higher in the segment of pharmaceuticals with generic competition. When looking at the matching rate over time, the rate is relatively stable for both segments, with only minor fluctuations between years (see Figure 30 in Appendix 1).

Figure 16. Swedish matching rate for pharmaceuticals with generic competition

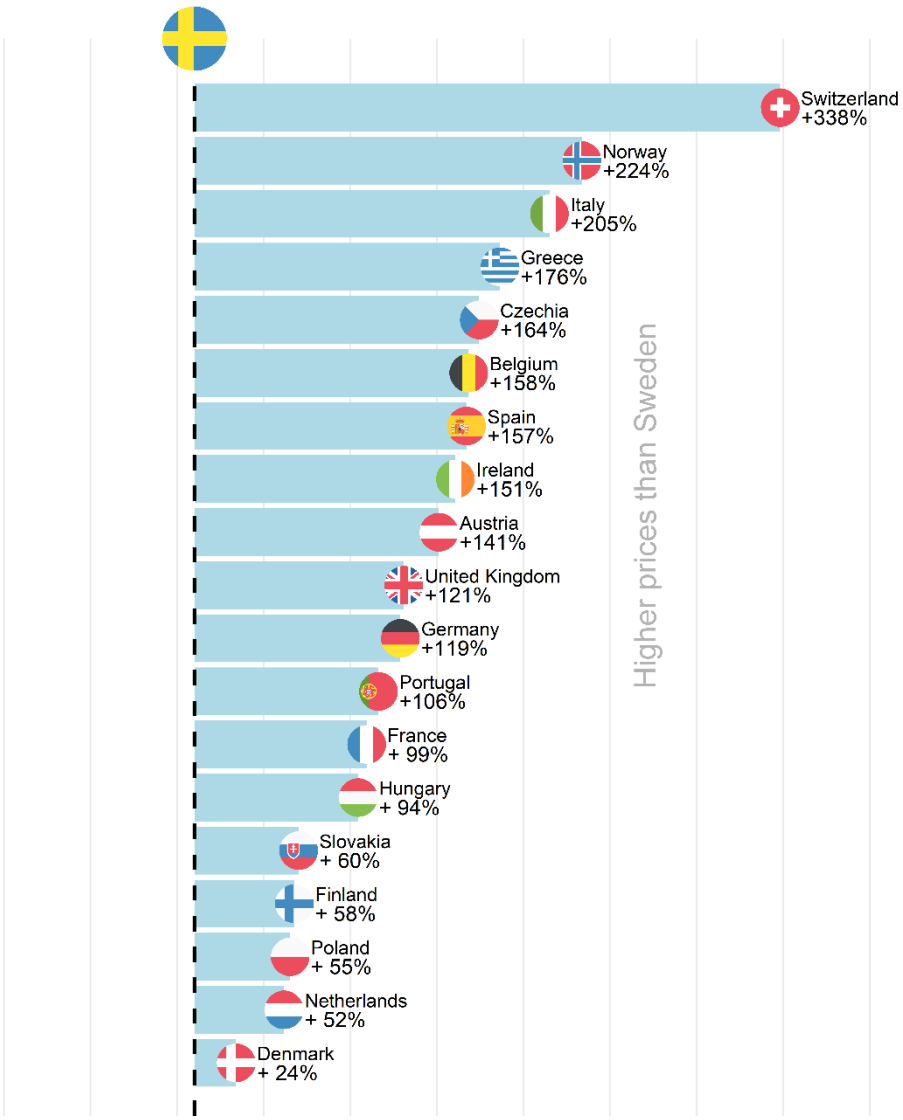


Source: IQVIA and TLV analysis.

3.3.2 Bilateral price comparison for pharmaceuticals with generic competition, 2022

Figure 17 shows that relative prices in relation to Sweden differ significantly. The figure compares the prices of pharmaceuticals available in Sweden with respective country included in the analysis, weighted by Swedish sales volumes in 2022. As the pharmaceuticals used in different countries differ, it is therefore not possible to compare the different countries with each other.

Figure 17. Bilateral price comparison for pharmaceuticals with generic competition, 2022



Source: IQVIA and TLV analysis.
Note: Prices during Q1 2022. Volume relates to March 2022, 12-month rolling average.

Figure 17 shows that Switzerland has more than three times higher list prices of pharmaceuticals with generic competition found in both Sweden and Switzerland. Denmark, which has the 5th highest matching rate in this segment, has 24 percent higher prices than Sweden.

Denmark has a system similar to the Swedish product-of-the-month system for generic competition. However, the systems differ in some aspects. For example, Denmark uses sales periods of two weeks as opposed to Sweden, which uses sales periods of one calendar month. In addition, Denmark does not have a ceiling price system like that of Sweden.[27] The Swedish ceiling price system discourages price increases and pushes down the price of pharmaceuticals that continue to have high prices even after generic competition has arisen. The ceiling price system has kept pharmaceutical prices down in Sweden over the past year, when inflation has been

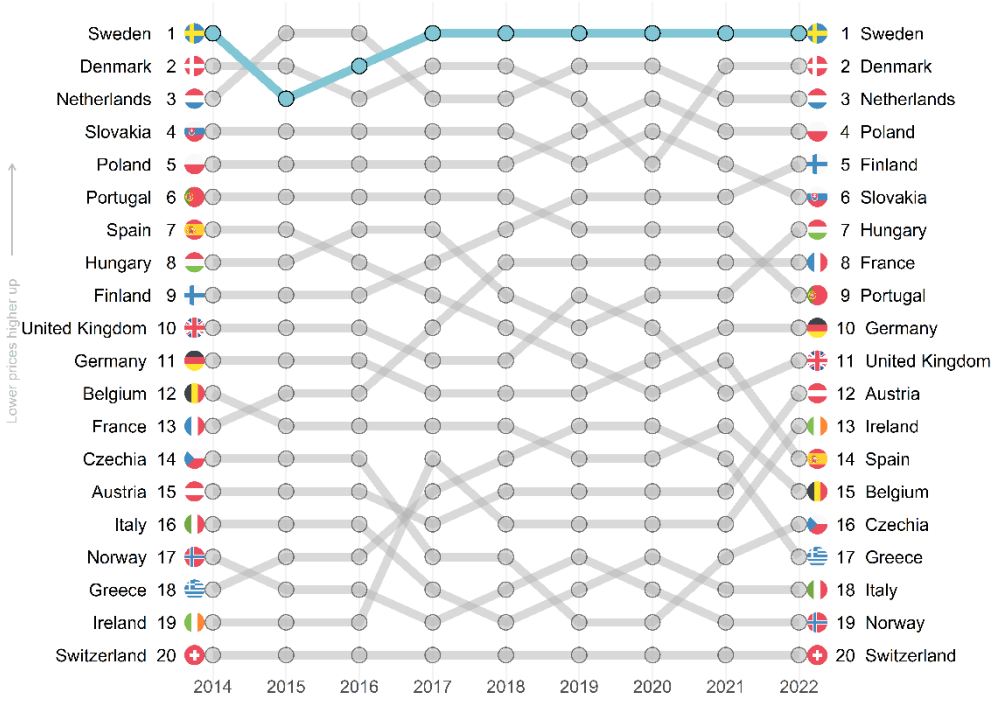
[27] Danish Medicines Agency (2019) Priser på medicin

high. This may be a contributing factor to the fact that in the latest price comparison Denmark has 24 percent higher prices than Sweden, compared to last year's price comparison when they had only 7 percent higher prices. Even within this segment, other countries may have different types of repayment agreements that are not reflected in the official list prices.

3.3.3 Historical development

Figure 18 shows the development of bilateral price comparisons over time for pharmaceuticals with generic competition. As volumes are weighted by sales in Sweden, comparisons with countries other than Sweden should be avoided. Throughout the period 2014-2022, Sweden's prices have been among the lowest.

Figure 18. Development of the bilateral price comparison over time, 2014–2022. Pharmaceuticals with generic competition

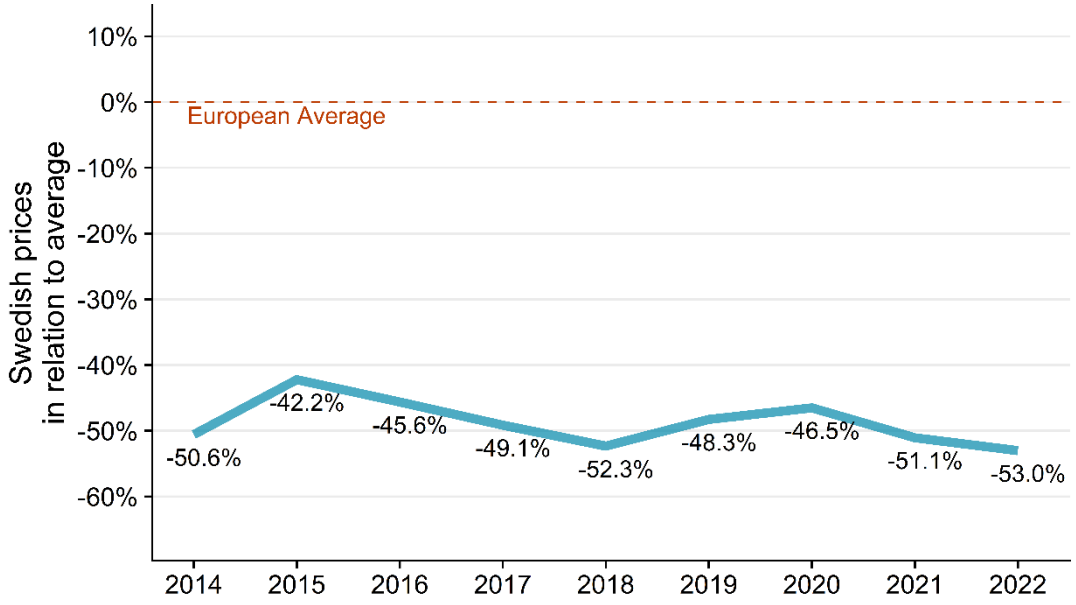


Source: IQVIA and TLV analysis.
Note 1: Rank 1 means that the country has the lowest prices.
Note 2: As the bilateral comparison uses Sweden's volume weights, interpretations between countries other than Sweden should not be made.
Note: Some countries have general discount systems that are not shown in list prices and may give a potentially different picture than the one shown here.

Figure 18 shows that Denmark has been closest to Swedish price levels for much of the period, with the exception of 2019–2020 when Denmark fell to fifth place at its lowest. Finland has moved from ninth place to fifth. Meanwhile, Switzerland has had the highest prices among the 20 countries included in the comparison throughout the time series. In the segment of pharmaceuticals with generic competition, the Swedish exchange rate has less impact than for pharmaceuticals without generic competition. However, the competitive situation in the PV system has a significant impact (see Figure 20 for drivers).

Figure 19 shows how Sweden's prices for pharmaceuticals with generic competition compare percentage-wise with the average for all countries included in the price comparison.

Figure 19. Sweden's relative prices compared to the average per year, calculated as a cross-section. Pharmaceuticals with generic competition



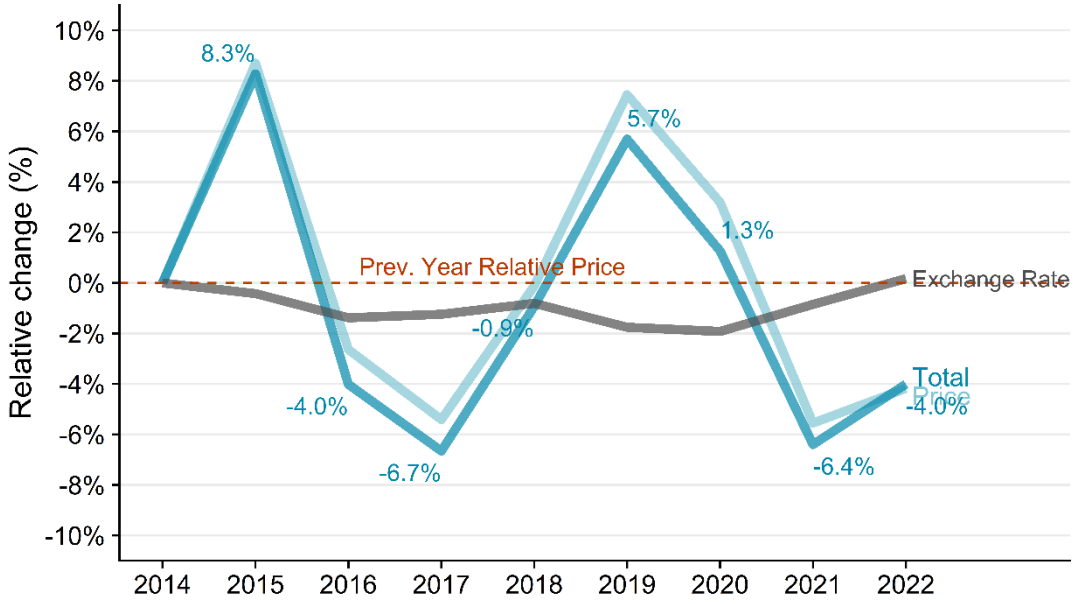
Source: IQVIA and TLV analysis.
Note: Calculation as a cross-section.

In 2022, Sweden's prices for pharmaceuticals with generic competition were 53 percent lower than the average for the other 19 countries. This is slightly lower than the level for 2014. Both the exchange rate and the competitive situation in the different substitution groups changed during the period. The competitive situation is constantly changing. A larger number of companies in a substitution group tends to increase price competition, while a smaller number tends to decrease competition.

3.3.4 Price and currency effects

Figure 20 shows a breakdown of how much of the relative price change is due to currency changes plus price changes between 2014 and 2022. Price changes are changes to the relative price due to actual price changes for pharmaceuticals, e.g. as a result of increased competition within a substitution group.

Figure 20. Relative price's change effects broken down by price and currency changes. Pharmaceuticals with generic competition weighted by 2014 use in Sweden.



Source: IQVIA and TLV analysis.

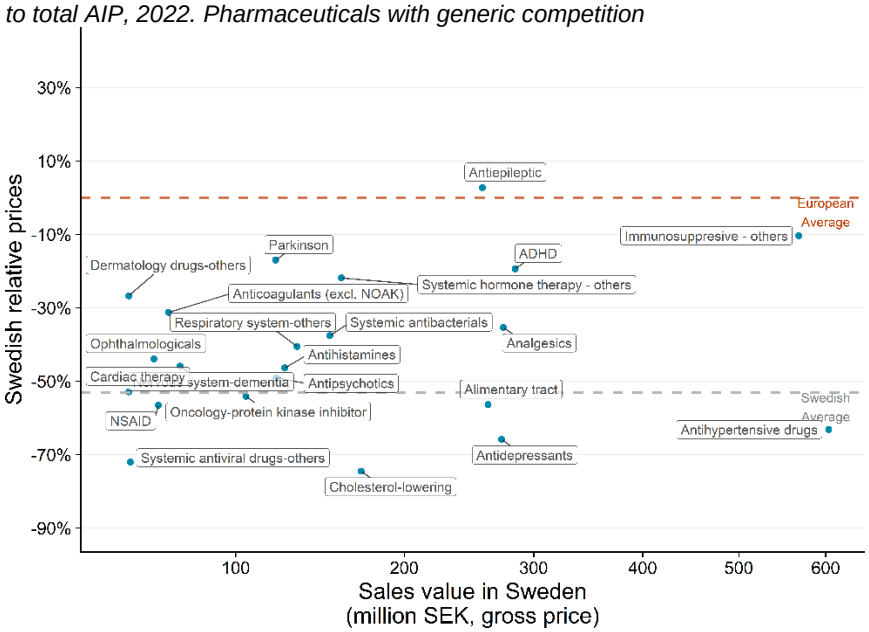
The currency effect is smaller than for pharmaceuticals without generic competition, which is also reasonable given that there is some scope for pharmaceuticals with generic competition to adjust prices based on a changed exchange rate. For pharmaceuticals in the PV system, the price can be increased up to the ceiling price without the company having to provide evidence justifying the need for a price increase in its application to TLV. The exchange rate effect that has such a strong impact on the price picture for pharmaceuticals without generic competition can thus be compensated for in this segment by higher prices, which is one of the explanations why the exchange rate effect is not as strong in the segment with generic competition, but the price effect is all the greater. Price changes can also be explained by competition within the PV system.

3.3.5 Pharmaceutical classes

As shown earlier, Swedish prices for pharmaceuticals subject to generic competition are generally lower than in other European countries. Figure 21 shows Sweden's prices in comparison with Europe, as well as sales in Sweden in 2022[28], broken down by pharmaceutical class. Only the classes with the highest sales are shown in the figures below.

[28] The sales total is calculated as the price range in Q1 2022 multiplied by the rolling 12-month volume of the respective pharmaceutical in Q1 2022.

Figure 21. Swedish prices for pharmaceutical classes compared to European average AIP, in relation to total AIP, 2022. Pharmaceuticals with generic competition



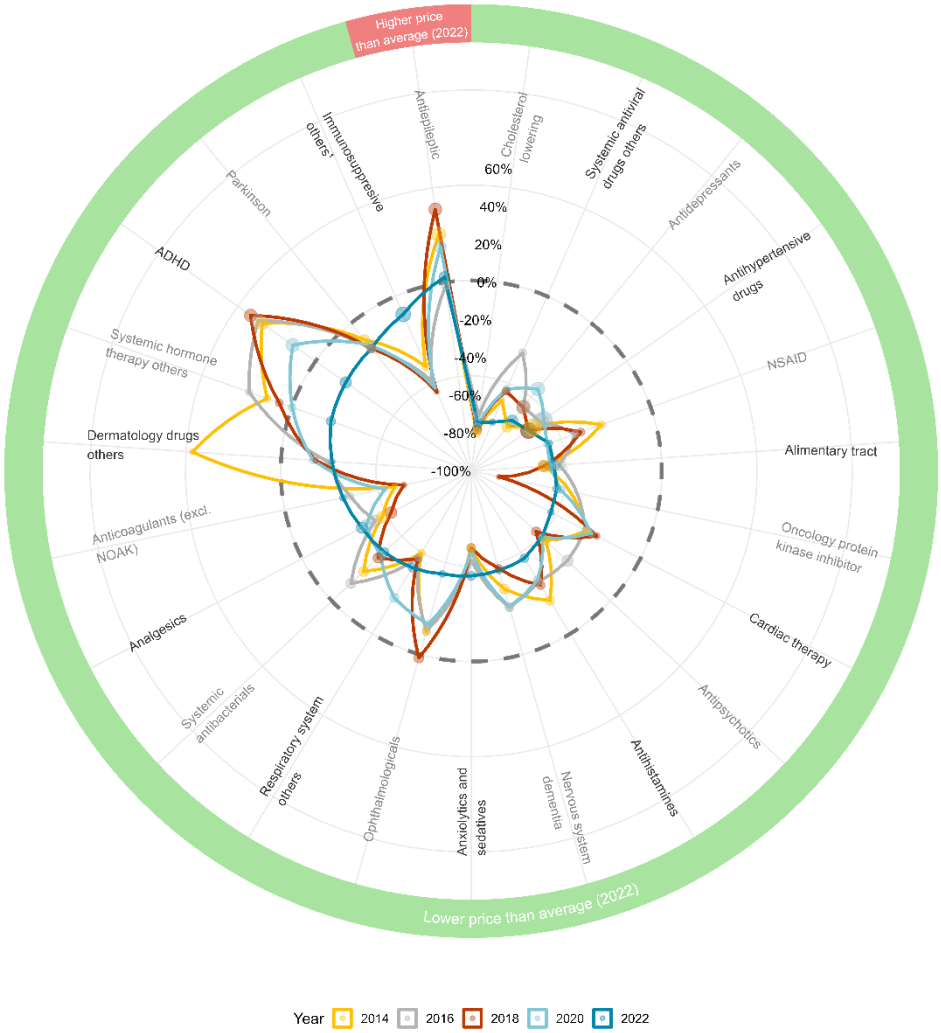
Source: IQVIA and TLV analysis.
Note: The x-axis intervals increase exponentially so that all pharmaceutical classes can be shown together. Pharmaceutical classes with AIP sales of less than SEK 50 million have been excluded for the same reason.

Swedish prices for pharmaceuticals subject to generic competition are generally lower than in other European countries. Figure 21 shows pharmaceutical classes with the highest sales, and in this selection only “Antiepileptics” is above the EU average. The Swedish Medical Products Agency has determined that pharmaceuticals for the treatment of epilepsy are not substitutable with other pharmaceuticals with the same substance, even though these are bioequivalent.[29] However, generic pharmaceuticals may be recommended for new patients in the treatment of epilepsy.

The substitution of ADHD medicines is also limited because in about 40 percent of all prescriptions filled, the prescriber, pharmacist or patient has ticked that the prescribed medicine should not be substituted at the pharmacy. Similar patterns are also found in other pharmaceutical classes, where substitution does not take place because either the patient, the prescriber or the pharmacy objects to the substitution. The relationship between the proportion of ticks and relative prices suggests that limitations on substitution impacts on the effectiveness of price competition within individual pharmaceutical classes.

[29] Swedish Medical Products Agency (2019), Läkemedel vid epilepsi – behandlingsrekommendation

Figure 22. Swedish prices for pharmaceutical classes compared to European average AIP, 2014–2022. Pharmaceuticals with generic competition



Source: IQVIA and TLV analysis.
Note 1: Green: Prices below the European average 2022 (more than two percent below); Grey: Prices around the average 2022 (between 2 percent below and 2 percent above) and Red: Prices above the European average 2022 (more than 2 percent above).
Note 2: [1] indicates that managed entry agreements existed for the pharmaceutical class in 2022. [2] indicates that managed entry agreements existed in other years for the pharmaceutical class.

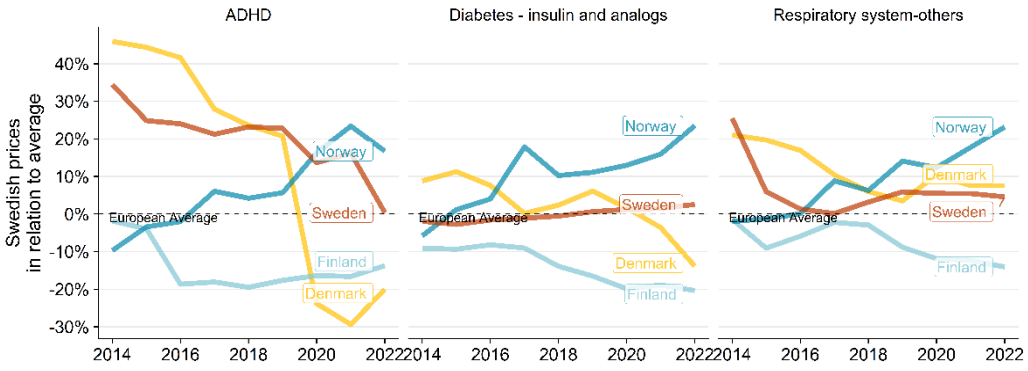
Figure 22 shows that the relative price in the pharmaceutical class “Antiepileptics” (the only one above the average in 2022) decreased between 2018 and 2022. The levels in 2022 are similar to the level Sweden was at in 2016. Figure 22 also shows that the prices of ADHD medicines have decreased in relation to the EU average over the last year.

3.4 Price comparison – Nordic outlook on selected pharmaceutical classes

This section highlights three top-selling pharmaceutical classes where intra-class substitutability is limited for various reasons. The classes included are “Diabetes – insulin and analogs”, “Respiratory system – others” (including asthma/COPD medicines) and “ADHD”.

The class “Diabetes – insulin and analogs” contains biosimilars which, although they are in principle equivalent products, are not substitutable in the same way as generic products. Benefit costs in this class amounted to SEK 2.9 billion in Sweden in 2021.[30] The “Respiratory system – others” pharmaceutical class, largely represented by asthma/COPD medicines, also had large sales volumes during the same period, amounting to SEK 1.8 billion in benefit costs in 2021.[32] In this class, generic alternatives are available but are not offered to patients to the extent of other pharmaceutical classes as the medicine is administered with an administration aid (inhalers), which may be technically different. For the pharmaceutical class “ADHD”, with 1.2 billion in benefit costs in 2021 [32], substitution to cheaper alternatives is limited due to prescribers, pharmacists or patients largely choosing to object to generic substitution, as described in the previous section.

Figure 23. Price development for the pharmaceutical classes “ADHD”, “Respiratory system – others” and “Diabetes – insulin and analogs” in the Nordic countries



Source: IQVIA and TLV analysis.
Notes: Prices for Q1 of the respective year. Volumes are for March of the respective year and 12 months back in time. Fixed three-year average exchange rate from 2014.

Figure 23 shows the relative pharmaceutical prices of Sweden, Norway, Denmark and Finland compared to the EU average for the selected pharmaceutical classes during the period 2014–2022. The figure uses a three-year average exchange rate for 2014, which means that the countries' exchange rates are held constant over the entire period under review. In the “ADHD” class, we see a clear decline in prices over time, mainly in Denmark and Sweden, with the largest change from 2019 onwards. The “Respiratory system – others” class shows a clear decline between

[30] TLV (2022) Uppföljning av läkemedelskostnader 2022

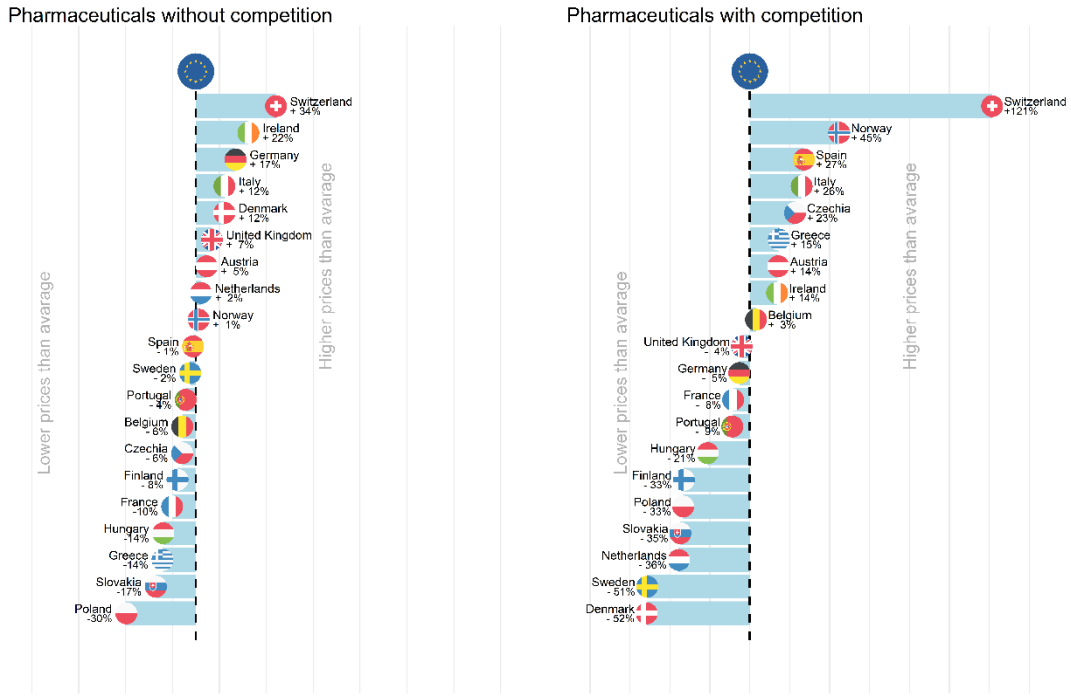
2014 and 2017 in terms of Sweden's relative prices, from 25 percent above the average to around the average. Sweden then reaches levels around 5 percent above the average in the subsequent years. For the “Diabetes – insulin and analogs” class, relative prices increase at a steady pace over the period 2015–2022, peaking in 2022 at around 2 percent above average. Despite clear price reductions in two of the groups, Sweden's prices remain at or slightly above the EU average in all three pharmaceutical classes, while Finland's prices remain below average in all classes throughout the period. Norway shows a relative increase in prices in all classes and remains above the EU average for most of the time period.

3.5 Bilateral average – price comparison given other countries' volumes

The analyses presented in the previous chapters are mainly based on Swedish conditions and prices. Pharmaceuticals with high use in Sweden have been given greater weighting than prices for pharmaceuticals with low use in Sweden, even if the use has been high in other countries. This means that Swedish prices may appear low, as Sweden may have lower prices for pharmaceuticals that are widely used domestically. The relationship may also be reversed, i.e. Swedish healthcare tends to prescribe low-priced medicines rather than high-priced medicines.

Figure 24 presents an alternative analysis, where the bilateral index is calculated using all countries' pharmaceutical use. Bilateral indices have been created for all countries based on the countries' own product basket and use. An average of these indices is then calculated. See Appendix 2 for a more detailed description of the methodology.

Figure 24. Price comparison with bilateral average for pharmaceuticals without and with generic competition, 2022. The exchange rate is the rolling 3-year average.



Source: IQVIA and TLV analysis.

For pharmaceuticals without generic competition, Sweden's prices are two percentage points lower than the average. This puts Sweden in tenth place on the list of lowest prices out of all 20 countries. This can be compared with Figure 9, which shows the bilateral index weighted by Sweden's sales volumes. According to this index, Sweden has the fifth lowest prices. Sweden's price level thus looks slightly higher when taking into account the use of pharmaceuticals in other countries compared to when only Swedish sales volumes are taken into account. This indicates that pharmaceuticals that are widely used in Sweden tend to have lower relative prices.

For pharmaceuticals with generic competition, Sweden has the second lowest prices in 2022, after Denmark. This is different from the bilateral index in Figure 17, where Sweden has the lowest price when only Swedish sales volumes are taken into account.

4 Discussion

In this report, Swedish pharmaceutical prices have been analysed from an international perspective, comparing prices with 19 other European countries. In the analyses, TLV focuses mainly on prices for prescription pharmaceuticals dispensed in retail pharmacies, as these are included in the pharmaceutical benefits managed by TLV.

The results show that, based on Swedish use, Sweden has relatively low prices for pharmaceuticals compared to the other countries included in the analysis, especially for pharmaceuticals with generic competition – where Swedish prices are among the very lowest. For pharmaceuticals without generic competition, Sweden has the fifth lowest prices in the analysis. The results also show that Swedish prices relative to other countries are at comparable levels to those reported in last year's report.[31]

The downward trend in prices is largely explained by the change in the exchange rate of the Swedish krona against the euro. Between Q3 2020 and Q4 2021, the krona strengthened against the euro, a trend that reversed in 2022 as the krona returned to levels similar to those observed in Q3 2020. As a three-year rolling average exchange rate is used in most of the comparisons, the effect remains persistent, but at a declining rate. If the effect of the changed exchange rate is removed, Swedish prices, relative to other countries, are only marginally lower over time. The fact that the analysis is largely influenced by changes in exchange rates means that the low relative price level reported in this year's report, and also identified in previous years' reports, [33,32,33] may change in the future if the exchange rate changes.

In the Swedish system, which is based on value-based pricing, no account is taken of exchange rates. Prices are instead determined based on Swedish conditions. Thus, prices do not automatically increase in the Swedish system when the exchange rate falls. If the exchange rate strengthens, this will lead to an increase in pharmaceutical prices in Sweden in relation to other European countries. TLV continues to monitor developments in price levels in European countries.

Based on the life cycle analyses presented, it is evident that Sweden's relative pharmaceutical prices are in line with other countries during the early post-marketing period of a pharmaceutical. For pharmaceuticals 5 to 15 years post-marketing, Swedish prices do not change much. Compared to European countries, Sweden has historically been above average for this segment, but according to more recent data, this interpretation is no longer as clear-cut. The absolute price level in other countries decreases in the years after introduction, while Sweden's absolute prices usually remain unchanged. After about 15 years on the market, the patent protection of the pharmaceuticals expires and the original pharmaceuticals can be replaced by generic alternatives, if available. The Swedish product-of-the-month

[31] TLV (2021) Internationell Prisjämförelse 2021
[32] TLV (2020) Internationell Prisjämförelse 2020
[33] TLV (2019) Internationell Prisjämförelse 2019

system,[34] with generic substitutability at pharmacies, creates significant price pressure that leads to Swedish prices generally falling sharply after 15 years, including in relation to other countries.

For some older pharmaceuticals, no generic competition arises. There may be several reasons for this. Certain pharmaceuticals with the same substance, dosage form and strength are not considered substitutable by the Swedish Medical Products Agency, as substituting different products could be associated with certain risks (e.g. antiepileptics), nor are biological drugs (reference drugs and biosimilars) considered substitutable by the Swedish Medical Products Agency.

The prices analysed in this report do not take into account any confidential discount agreements (managed entry agreements) that countries may have for certain pharmaceuticals and that affect what the countries ultimately pay for these. The total value of managed entry agreements in Sweden in 2021 was equivalent to SEK 2.7 billion.[35] At present, we lack information on possible discount agreements in other countries, which makes it difficult to fully control for the effect of these agreements on the results in the analyses. Although it is not possible to control for these agreements in the analyses, it is likely that the results presented in the report give an indication of the actual price level between countries. In cases where Sweden does not have a managed entry agreement for a pharmaceutical, but has a higher list price than other countries, we know with certainty that Swedish prices are higher than in other countries. If the other countries also have discount agreements for these pharmaceuticals, the price difference is even larger than what we observe in the list prices, but it is not possible to show exactly how much larger. In cases where Swedish list prices are relatively low and other countries have discount agreements, we also do not know what the actual price difference is (e.g. TNF-alpha inhibitors).

The type of comparisons made here should be interpreted in light of the pharmaceutical pricing systems applied in the different countries. Sweden uses a value-based pricing system,[36] where the price accepted for a pharmaceutical must be reasonable in relation to the health benefit of the pharmaceutical. TLV's assignment is to ensure cost-effective use throughout the pharmaceutical's life cycle. Thus, Sweden differs from most other European countries, where prices are set relative to selected reference countries, known as IRPs. IRPs do not take into account drug efficacy, as Sweden does, and use in everyday clinical practice, which by its nature is not always available until a pharmaceutical is in use and has been on the market for some time. The analysis shows that there are differences in the way different countries deal with price changes, in the short and longer term. Swedish prices tend to remain unchanged in the medium term, while in other countries they tend to decrease. In the longer term, prices decrease more in Sweden compared to other countries. Generally speaking, it is difficult to draw clear conclusions about the relative price situation in different countries because of the existence of hidden prices.

[34] TLV (2022) Periodens varor
[35] TLV (2022) Prognos av besparingar från sidoöverenskommelser helåret 2022
[36] TLV (2022) Utveckling värdebaserad prissättning

TLV makes subsidy decisions by assessing whether the cost of treatment is reasonable in relation to the benefit of the treatment based on the circumstances prevailing at the time of the decision. However, these conditions may change over the life cycle of a pharmaceutical. For example, new pharmaceuticals may be introduced, the price of other pharmaceuticals may decrease or new knowledge about the efficacy of pharmaceuticals may become available. In order to create the conditions for cost-effective use of pharmaceuticals over time, TLV monitors and evaluates the decisions taken within the pharmaceutical benefits scheme. The price considered reasonable when a pharmaceutical is first introduced into the benefit scheme does not necessarily remain so throughout the entire life cycle of the pharmaceutical. This may be due to a number of reasons, such as changes in the pharmaceutical market due to the introduction of new treatment options, competition between pharmaceuticals, or the fact that the pharmaceutical did not demonstrate the same efficacy in everyday clinical practice as assumed at the time of the subsidy decision. To ensure value-based pricing, TLV monitors the pharmaceuticals that have been granted a subsidy and, if necessary, adjusts the prices and the benefit status. TLV also adjusts prices through use of rule-based price adjustments via the 15-year rule, the product-of-the-month system and the ceiling price system.

In an ongoing government assignment, *Making data available for the evaluation of pharmaceutical use and efficacy*, TLV is developing methods to make it possible to monitor drug treatment, in terms of both use and efficacy, in clinical practice. [37] In another government assignment, *Long-term sustainable financing of pharmaceuticals*, TLV is investigating the options for implementing cost-containment measures that will lead to a more cost-effective use of pharmaceuticals.

Similar to previous years' international price comparisons by TLV, this year's report also highlights the importance of continuously reviewing and evaluating past pricing and subsidy decisions for pharmaceuticals. An international comparison provides an indication of how the Swedish system works in an international context. A great deal is happening in the external environment, with inflation, system changes and exchange rate changes. TLV intends to continue to monitor how the Swedish system compares with other countries.

[37] Government of Sweden (2022), Ministry of Health and Social Affairs, Regleringsbrev 2022 Myndighet Tandvårds- och Läkemedelsförmånsverket

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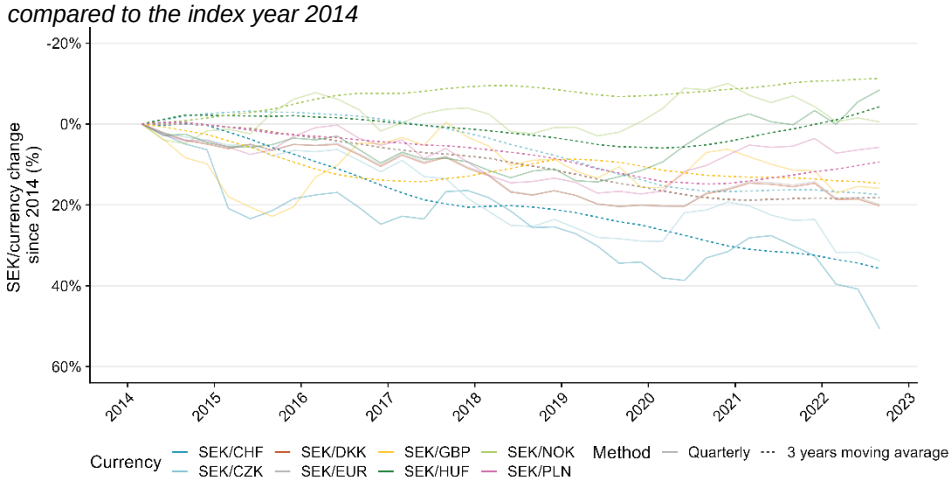
1 Appendix 1: Sensitivity analyses

1.1 Exchange rate

The exchange rate has a major impact on how Swedish pharmaceutical prices compare to those of other countries from an international perspective. When a new pharmaceutical starts to be sold on the Swedish market at a fixed price, the cost of this product relative to countries with other currencies will decrease if the Swedish krona weakens.

Figure 1 illustrated how the Swedish krona has performed against the euro over time. Figure 25 shows the exchange rate change over time for all currencies of the comparison countries. Each colour is associated with an exchange rate and each exchange rate has two lines, one showing the average exchange rate per quarter (semi-transparent) and one showing the average exchange rate with a three-year rolling average (dashed line). As the y-axis is inverted, a falling line means that the Swedish krona has lost value compared to the reference currency (i.e. more expensive to convert to the currency in question) while a rising line means the opposite. Each exchange rate is compared to the 2014 rate, so the y-axis shows the percentage change since the index year 2014.

Figure 25. Percentage change in the exchange rate of all comparison countries' currencies over time compared to the index year 2014

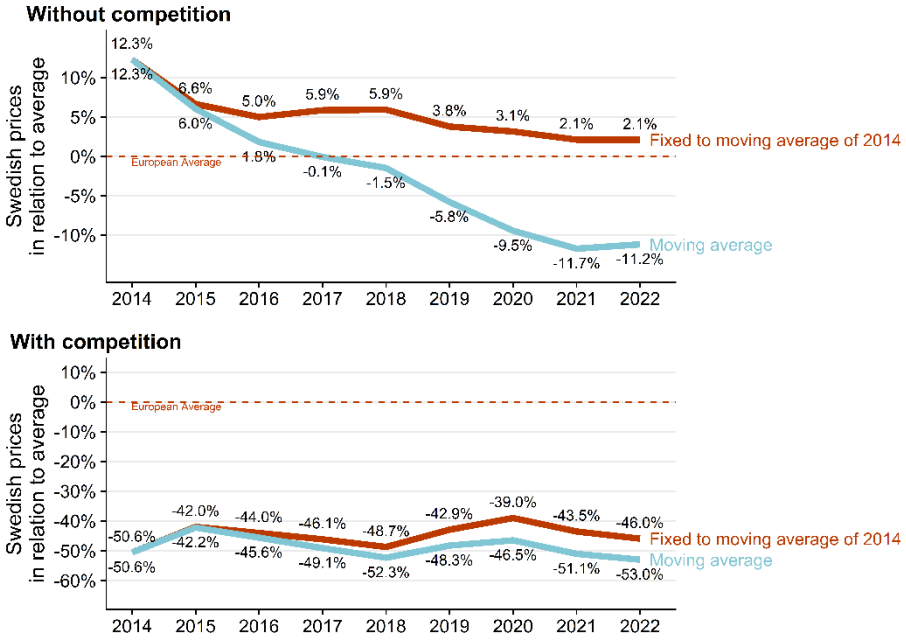


Source: Eurostat
Note: SEK/currency change since 2014 (%); percentage change in the number of SEK per currency since Q1 2014.

The value of the Swedish krona has increased against the Norwegian krone (NOK) by around 10 percent and the Hungarian forint (HUF) by around 1 percent in Q1 2022 compared with the index year 2014 (3-year rolling average). For other currencies, Sweden has depreciated since the index year 2014, with the krona showing the largest decline against the Swiss franc (CHF). On average, the Swedish krona has depreciated by 17 percent (quarterly) and 13 percent (3-year rolling average) in Q1 2022 compared with the index year 2014.

In recent years, the Swedish krona has weakened against the euro. As the 3-year average is used throughout the report, 2022 has also been affected by a falling Swedish krona, but at a declining rate over the past year. One way to look at the impact of the exchange rate is to fix the exchange rate between e.g. SEK and EUR to an exchange rate prevailing at a certain point in time and then compare prices.

Figure 26. Sweden's relative prices compared to the average per year calculated as a cross-section. Pharmaceuticals without and with generic competition



Source: IQVIA and TLV analysis.
Note: Exchange rate broken down into 3-year running average and fixed 3-year running average for 2014.

Figure 26 (top graph also shown in Figure 12) shows how Sweden's relative pharmaceutical prices evolved between 2014 and 2022 with a rolling exchange rate and a fixed 3-year average exchange rate from 2014 for pharmaceuticals with and without competition. Fixing the exchange rate at the three-year average exchange rate from 2014 means that prices for all years are converted using the average exchange rate of the Swedish krona against the respective currencies in Europe between the years 2011 and 2014. For pharmaceuticals without generic competition with a three-year rolling average exchange rate, Sweden's relative prices have moved from around 12 percent above the average in 2014 to around 11 percent below the average in 2022 (see Section 3.3.3 for a more detailed description regarding pharmaceuticals without competition). If the currency is instead fixed at the three-year average exchange rate from 2014, Sweden's relative prices fall to just over two percent above the average.

If the exchange rate were to return to the 2014 level, all other things being equal, Swedish prices would be just over two percent above the average for all countries.

1.2 Alternative price measures

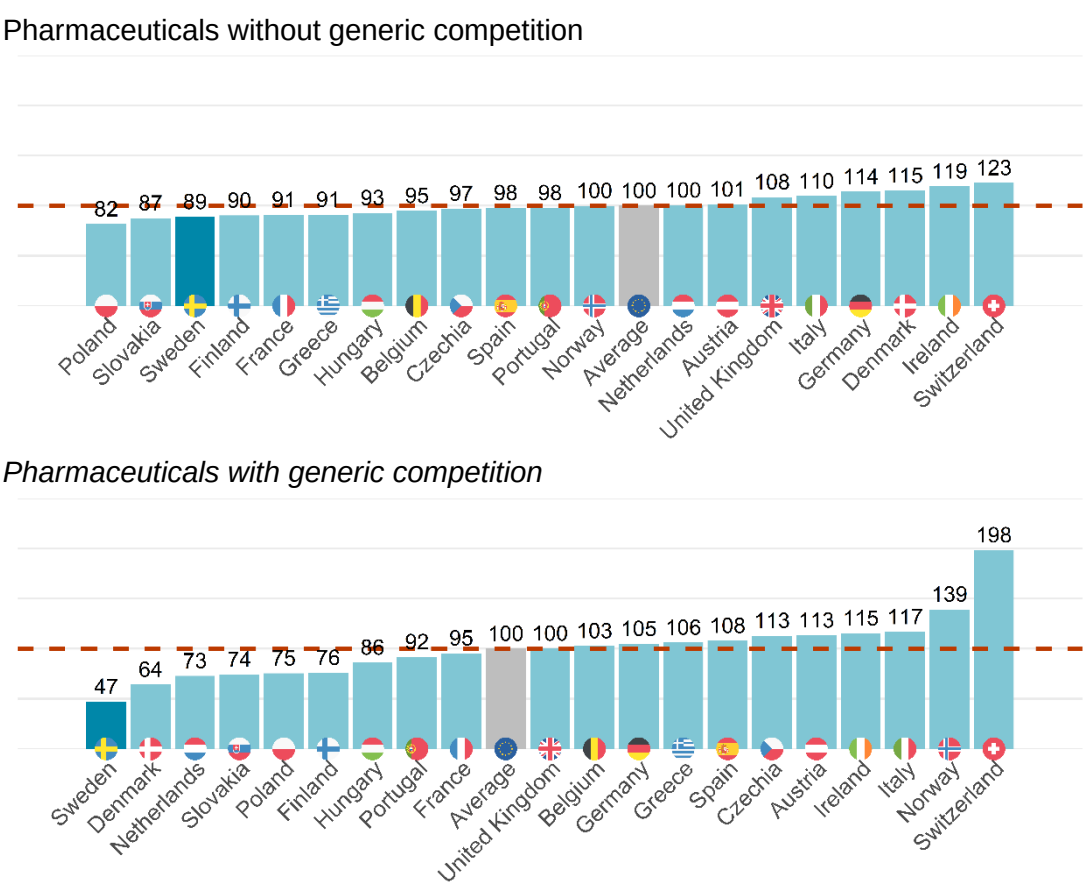
Comparing list prices for pharmaceuticals is complex, as the type of pharmaceuticals and the quantity of a pharmaceutical used differ between countries. Throughout the report thus far, bilateral price comparisons and bilateral averages have been used to compare prices between Sweden and the 19 other European countries included in the analyses.

The sample of pharmaceuticals remains those used in Sweden. However, the pharmaceuticals with low use in Sweden but higher use in other countries are also included. The base is the average price level in Europe, with an index of 100. An

index higher than 100 indicates a higher pharmaceutical price than the European average price. A pharmaceutical must be available in at least eight countries to be included in the comparison.

An alternative way of comparing pharmaceutical prices is by using a cross-sectional index. If a country lacks a pharmaceutical, the average for all other countries will be imputed instead. This means that the spread in prices in relation to the average is compressed against the average, especially for countries lacking many of the pharmaceuticals available in other countries.

Figure 27. Cross-sectional index, 2022. 3-year rolling exchange rate.



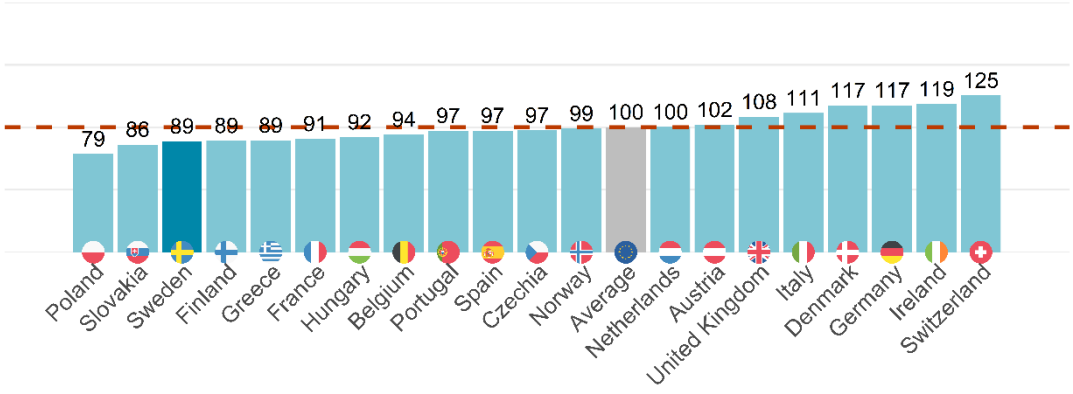
Source: IQVIA and TLV analysis.

According to Figure 27, Sweden has 11 percent lower prices for pharmaceuticals without generic competition than the average for all countries. For pharmaceuticals with generic competition, Sweden has 53 percent lower prices than the average.

1.3 The effect of managed entry agreements

In order to consider the effect of *managed entry agreements*, i.e. where the pharmaceutical companies make a repayment to the regions for part of the pharmaceutical costs, these pharmaceuticals are excluded in Figure 28. Repayment levels are confidential and can therefore not be compared or reported.

Figure 28. Cross-sectional index for pharmaceuticals without generic competition and without managed entry agreement, 2022 3-year rolling exchange rate.



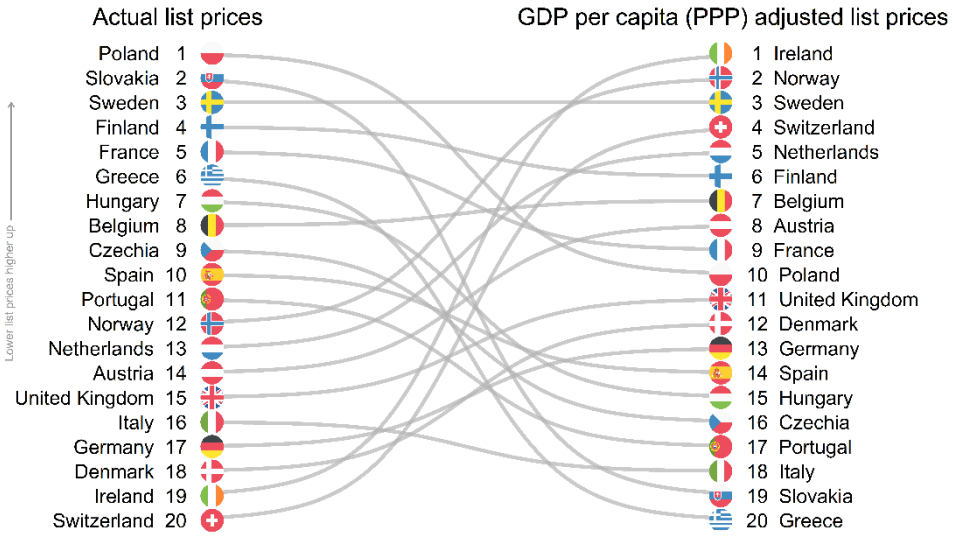
Source: IQVIA and TLV analysis.
Note: Prices during Q1 2022. Volumes rolling 12 months up to March 2021. 3-year average exchange rate. Excluding pharmaceuticals with managed entry agreements in Sweden. European average = index 100.

After excluding pharmaceuticals with managed entry agreements in Sweden (approximately five percent of the pharmaceuticals), Sweden remains in third place.

1.4 Purchasing Power Parity (PPP) benchmark

As a country's GDP (PPP) per capita can be assumed to impact the population's perception of a pharmaceutical's cost in relation to its disposable income or the cost of other types of goods, the analysis is made with PPP-adjusted prices.

Figure 29. Change of the price comparison in case of nominal pharmaceutical prices and adjusted pharmaceutical prices based on Purchasing Power Parity (PPP) GDP per capita. Pharmaceuticals without generic competition, 2022.



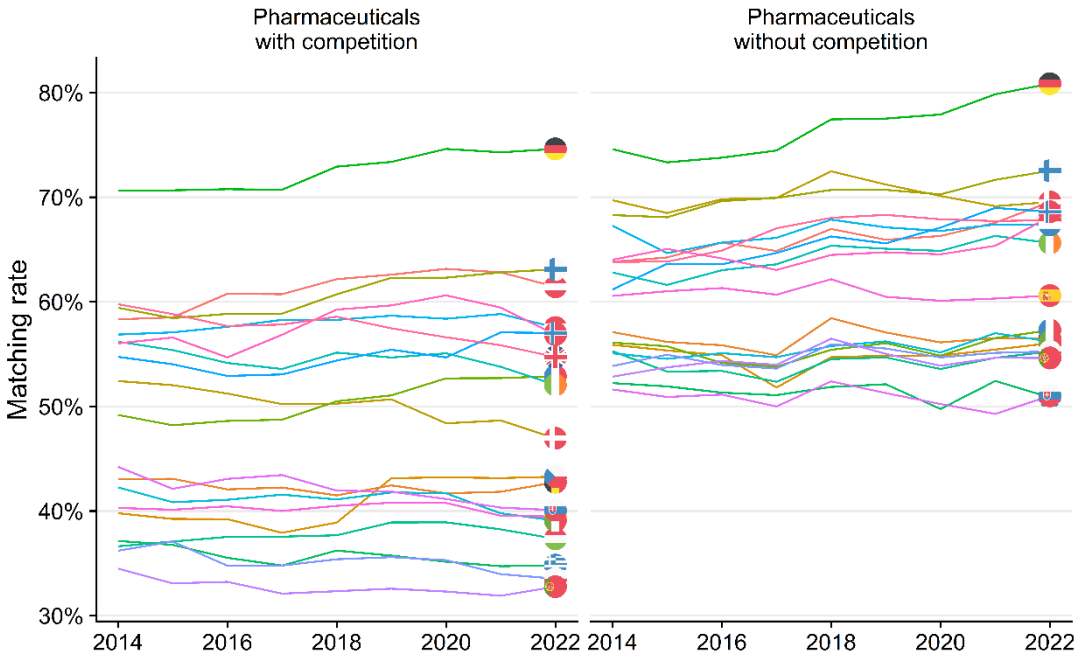
Source: IQVIA, IMF and TLV analysis.
Note: Rank 1 means that the country has the lowest prices. 3-year running average exchange rates per year.

In Figure 29 we see that when PPP-adjusted prices are used, some countries move a lot in relation to Sweden. The reason is that GDP (PPP) per capita differs greatly between countries. For example, Poland moves from first to tenth place, while Ireland moves from nineteenth to first place. However, Sweden remains in the same place, i.e. third place, even with PPP-adjusted prices.

1.5 Matching rate over time

The majority of the analyses in this report compare prices for pharmaceuticals with sales in Sweden with prices for the same pharmaceuticals in other countries. Figure 30 shows how the matching rate varies over time for the comparison countries included in the analyses. The matching rate shows the proportion of prescription pharmaceuticals sold at pharmacies in Sweden that are also available in other countries with the same limitation. The figure shows a relatively stable matching rate for each country over time, for pharmaceuticals both with and without generic competition. Generally speaking, the comparison countries have a higher matching rate in the pharmaceuticals with generic competition segment.

Figure 30. Matching rate for pharmaceuticals sold in Sweden compared to other countries. Broken down by year, country, and competition status of the pharmaceutical.

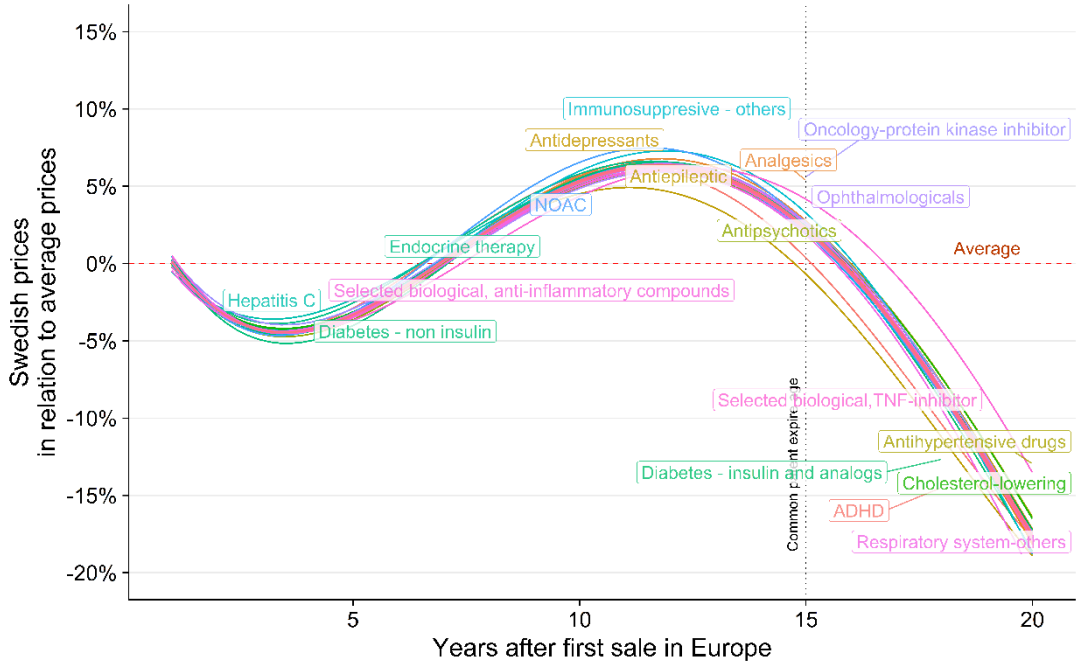


Source: IQVIA and TLV analysis.

1.6 Life cycle analysis in which pharmaceutical classes and countries are excluded one by one

In order to examine how Sweden's relative prices over the life cycle of pharmaceuticals are affected by different pharmaceutical classes, each pharmaceutical class has been excluded from the analysis, one at a time. Figure 31 shows each life cycle analysis with a specific pharmaceutical class excluded, and the pharmaceutical classes that on average affect Sweden's relative prices the most also have their names visualised at the age at which the difference was greatest. The curve follows similar trends to that seen in Figure 4. The largest impact on the curve occurs between years 15 and 20, where the exclusion of pharmaceutical classes such as “Selected biological, TNF inhibitors” reduces the distance of average Swedish relative prices from the EU average, while the class “Antiepileptics” does the opposite. This shows, for example, that “Selected biological, TNF inhibitors” is so much cheaper in Sweden that Sweden's relative prices would rise if that class were to be excluded from the analysis.

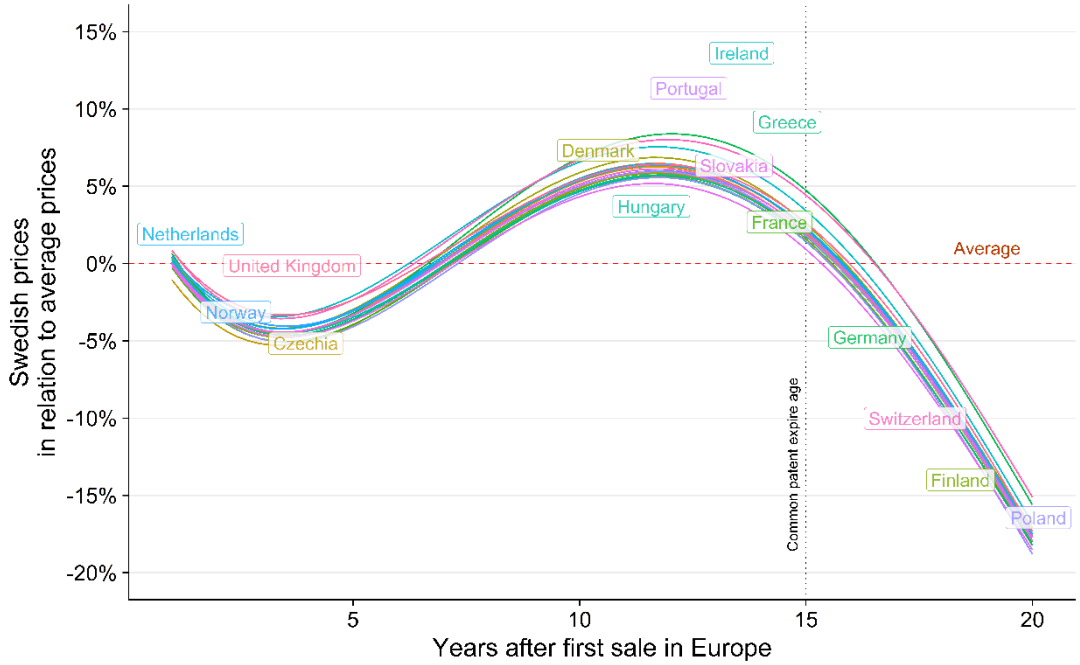
Figure 31. Sweden relative pharmaceutical prices 2014–2022 compared to the average price when one pharmaceutical class has been excluded in each estimation. Comparison is by year after marketing authorisation.



Source: IQVIA and TLV analysis.

In Figure 32, the same analysis is performed, but instead of excluding specific pharmaceutical classes, each comparison country is excluded one at a time. Only the countries with the largest average difference from the analysis in Figure 32 have the country indicated in the figure at the age at which the difference was greatest. We can see similar trends in this figure, where the spread among the different curves is slightly larger between year 15 and year 20, but overall the trend from Figure 4 persists. The countries with the largest impact on the average Swedish relative price over the life cycle in the later pharmaceutical ages follow the ranking that can be found in Figure 11, where the exclusion of Poland reduces the distance of average Swedish relative prices from the EU average, while the exclusion of Switzerland and Germany has the opposite effect.

Figure 32. Sweden relative pharmaceutical prices 2014–2022 compared to the average price when one comparison country has been excluded in each estimation. Comparison is by year after marketing authorisation.

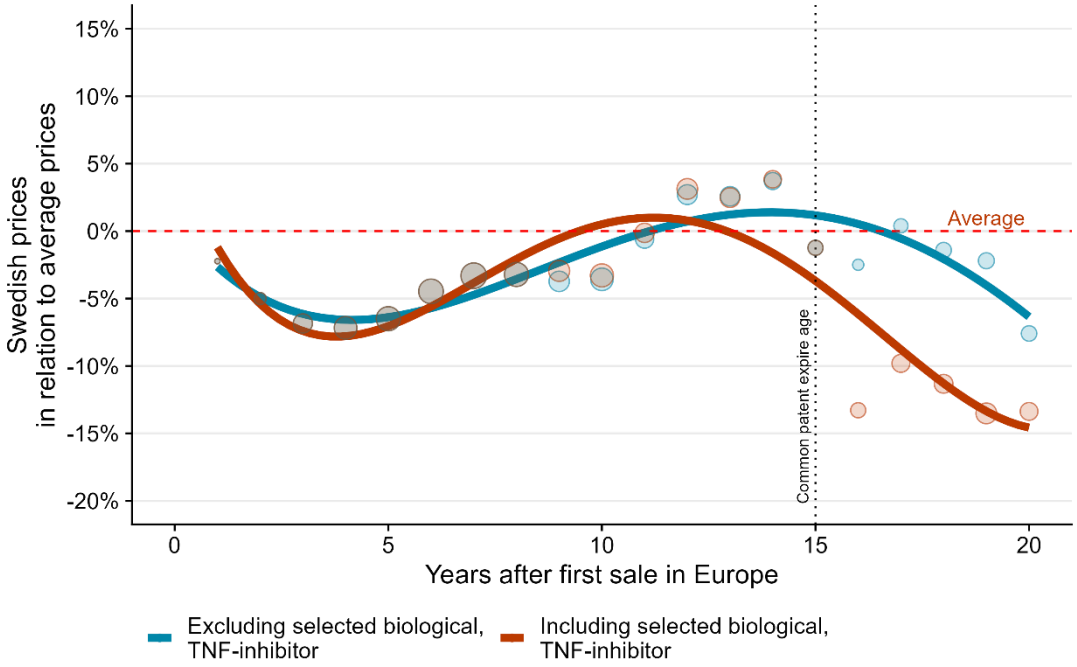


Source: IQVIA and TLV analysis.

1.7 Life cycle analysis with TNF-alpha inhibitors excluded and limited time period

Section 3 analysed the effect of limiting the period included in the analyses regarding Sweden's relative prices over the life cycle of a pharmaceutical. One of the pharmaceutical classes that had a major impact on Sweden's positioning in the report is TNF-alpha inhibitors, which could also be seen as the class that generated the largest effect on Sweden's relative prices over the life cycle between year 15 and year 20. In Figure 33, TNF-alpha inhibitors are excluded, and the time interval is limited to the years 2019–2022, as in Figure 5. When TNF-alpha inhibitors are excluded, the decrease is about 10 percentage points smaller between years 15 and 20.

Figure 33. Sweden's relative pharmaceutical prices 2019–2022 excluding TNF-alpha inhibitors compared to the average price for the 20 European countries in the report. Comparison is by year after marketing authorisation.



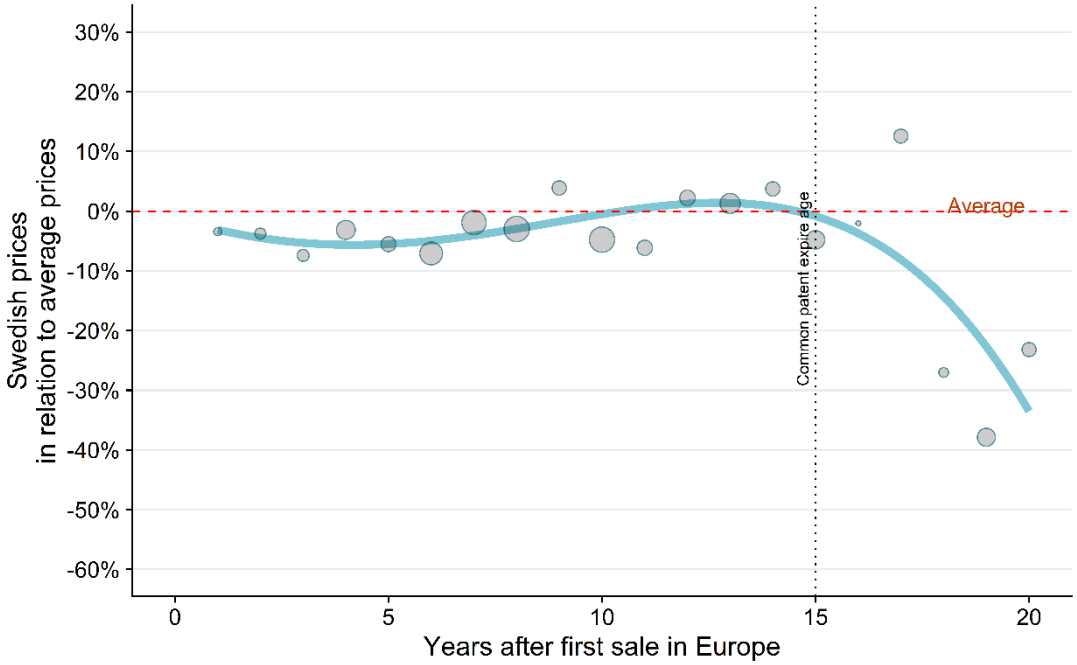
Source: IQVIA and TLV analysis.

1.8 Life cycle analysis limited to price data for 2022

As a final sensitivity analysis focusing on Swedish relative prices over the life cycle of a pharmaceutical, in Figure 34 the prices compared are limited to only those observed in 2022. Note that the y-axis differs from previous life cycle analyses, as the interval here is larger. Between years 1 and 10, Sweden's pharmaceutical prices are on average slightly closer to the European average, but remain below at most ages. Between years 10 and 15, the levels are comparable to those observed in Figure 33. Between years 15 and 20, Sweden has, on average, pharmaceutical prices below the European average, with lower levels than shown in the previous life cycle

analyses. At most, Swedish prices are on average 40 percent below the European average at age 19.

Figure 34. Sweden's relative pharmaceutical prices in 2022 compared to the average price of the 20 European countries included in the report. Comparison is by year after marketing authorisation.



Source: IQVIA and TLV analysis.

It is important to point out that only one year is observed for each unique pharmaceutical in Figure 34. This means that this figure contains fewer observations over the life cycle and only includes pharmaceuticals for which price data are available for 2022.

2 Appendix 2: Methodology and data

2.1 Segmentation based on competition status

The pharmaceuticals have been divided into segments based on the conditions for competition in Sweden. Pharmaceuticals that can be substituted by generic products are considered exposed to competition. These segments are:

- Pharmaceuticals without generic competition (outside the product-of-the-month system)
- Pharmaceuticals with generic competition (in the product-of-the-month system)

The pharmaceuticals without generic competition segment includes pharmaceuticals for which there has been no competition between at least two different substitutable pharmaceuticals in Sweden. The segment includes both patented pharmaceuticals and pharmaceuticals whose patent protection has expired, but where competition between two substitutable pharmaceuticals has not arisen. This segment usually also includes biosimilars as these are not directly substitutable with the reference product. These pharmaceuticals are included in the same segment because the Swedish Medical Products Agency considers these pharmaceuticals to be original pharmaceuticals, making pricing conditions the same as for original pharmaceuticals. However, competitive conditions may differ between the countries included in the comparison. The pharmaceuticals with generic competition segment (i.e. those in the PV system) include all pharmaceuticals included in the generic substitution in the product-of-the-month system in March of each year up to and including 2022.

2.2 Data set and pharmaceutical sample

The starting point in the analysis is the prescription pharmaceuticals in Sweden that have the highest sales and are covered by the benefits scheme. In this year's data set, the data has been supplemented with pharmaceuticals with the highest sales in Europe and new pharmaceuticals included in the latest edition of the EFPIA WAIT survey on time-to-market in different countries.

Before TLV's first report in 2014, IQVIA[38] was commissioned to deliver data for 200 substances in the patent-protected pharmaceuticals segment, 180 substances in the off-patent original pharmaceuticals without competition segment, and 200 substances in the off-patent pharmaceuticals with generic competition segment with the highest sales. Since then, the data has been updated each year and supplemented with new pharmaceuticals with high sales volumes. This also means that figures may vary between annual reports, as the sample of pharmaceuticals grows with each report iteration.

Price indices presented in the study are based on list prices and on the pharmacy purchase price (AIP) or equivalent. The reason for using AIP as a price measure is

[38] Prior to November 2017, IQVIA was called IMS Health.

that it does not include the pharmacies' trade margin, which may vary between countries depending on the way pharmacies are remunerated in each country.

Portugal, Germany, and Spain are countries with general discount systems that are not visible in list prices. Lack of complete information on possible discounts is a weakness in all price surveys. However, analyses of change over time, and specifically in this report – a comparison of the development of the same products during the period 2014 to 2022 – have a clear advantage. Assuming that any discounts are at a similar level from one year to the next, it provides a good comparison of the relative price development between different countries.

The table below shows how much of Sweden's sales are covered by the data on which the analysis is based. The input data for this report comes from IQVIA.

Table 2. Contribution margin of sales totals

Year	Total AIP IQVIA	Total AIP EHM	Contribution margin
2014	4,01	4,54	88%
2015	4,56	4,78	95%
2016	4,89	5,04	97%
2017	5,11	5,35	95%
2018	5,41	5,72	95%
2019	5,77	6,25	92%
2020	6,69	7,26	92%
2021	6,30	7,05	89%
2022	6,76	7,49	90%

Note 1: Data from IQVIA in relation to data from EHM. Sales of pharmaceuticals during Q1 between 2014 and 2022. AIP (pharmacy purchase price) level totals.
Note 2: Pharmacy preparations are not included in the comparison.

The sales value does not cover all sales of prescription medicines dispensed in retail pharmacies in Sweden, as only the top-selling substances in Sweden and Europe are included.

In the price comparison, reconciled prices for different product baskets of pharmaceuticals are analysed. The definition of a pharmaceutical may vary. Pharmaceuticals can be matched in different ways with different consequences for precision and in how many countries a pharmaceutical is included in the comparison.

In this analysis, a pharmaceutical is defined as a pharmaceutical with the same substance, dosage form and strength. The definition does not include pack size, as the choice of pack sizes used varies by country.

In Sweden, pharmaceuticals are normally collected at the pharmacy for a period of three months, while in southern Europe, it is normally a period of one month. This means that larger packs are normally sold in Sweden than in countries where collection takes place at more frequent intervals. If the pack sizes frequently sold have a lower price than those with lower sales, this would mean that large packs would be given greater weight, which would benefit Sweden in a price index. To correct for this, the price has been calculated as cost per unit for a specific substance, dosage form and strength. This means that different pack sizes can be compared, making the price indices more accurate. This approach increases the

matching rate with other countries, although the precision of the comparison is slightly lower than when matching at the pack level.

One alternative would be to match at the pack level, meaning the exact same pack in terms of substance, dosage, strength, and size needs to be available in both Sweden and the comparison country to be included. This method has a high degree of precision, as the pharmaceuticals match in terms of pack. At the same time, the risk is greater that a certain specific pack is not available in many countries. Pack size can often be linked to dispensing frequency. The longer time between filling of prescriptions/dispensing of the pharmaceutical, the greater the probability that larger pack sizes are commonly used, and vice versa.

Another alternative would be to measure the costs that each country has for a particular therapy group, regardless of which pharmaceuticals are used, and then weighting these costs together to see how much a country pays to treat different diagnoses. Problems with a price comparison of this type are difficulties in qualifying which pharmaceuticals belong to a particular therapy group and that treatment traditions may differ between countries.

2.3 Pharmaceuticals with a very low volume in a country are excluded

Some countries with a matching pharmaceutical in Sweden may have significantly lower sales volumes than Sweden. If the volume per capita is lower than 0.5 percent of that in Sweden, the pharmaceutical has been excluded from the calculation of bilateral indices that year. This is to avoid attributing a pharmaceutical with very little use in the comparison country disproportionate weight in the price comparison and thus potentially overestimating the relative price level. Volume data for the rolling 12 months up to March 2022 is used in the calculation.

2.4 Sales volumes and weighting

It is common practice to weight the prices of different pharmaceuticals in a price index by volume. Price differences on pharmaceuticals with high sales are then attached greater significance than pharmaceuticals with low sales and vice versa.

A price index is a weighted average of a number of pharmaceuticals, usually calculated over time. If we have two periods (period 0 and period t) and n pharmaceuticals, a general price index can be formulated as:

$$I_p = \frac{p_1^t w_1 + p_2^t w_2 + \cdots + p_n^t w_n}{p_1^0 w_1^0 + p_2^0 w_2 + \cdots + p_n^0 w_n} \times 100$$

Where p_i^t represents the price of pharmaceutical i at the time t and w_i represents the weight of pharmaceutical i. To calculate the relative importance of a pharmaceutical's price, sales volume q is usually used as a weight for a pharmaceutical. In this analysis, the index is calculated for one time period at a time, meaning period 0 and period t are the same. Time is replaced by country, abroad U and Sweden S.

The weighting can either be sales volume abroad or sales volume in Sweden. The choice determines whether the price index is to be interpreted from a Swedish perspective or not. The standard for price analyses in the pharmaceutical field is to

calculate the Laspeyres price index, i.e. using the country from which price differences are to be measured as base, in this case Sweden's:

$$L_p = \frac{p_1^U q_1^S + p_2^U q_2^S + \cdots + p_n^U q_n^S}{p_1^S q_1^S + p_2^S q_2^S + \cdots + p_n^S q_n^S} \times 100$$

Where p^U refers to price abroad and q^S quality in Sweden. If the price is the same in Sweden and abroad, the index value is 100. If the index is <100 (or >100), it means that the pharmaceutical has a lower (or higher) price abroad than in Sweden. In several figures in the report, percentages are used instead of indices, e.g. to show that a country has a price that is a number of percentage points above the average. Then, an average of the index for all countries is calculated and a country's index is divided by the average index. For example, if Sweden has an index of 100 and the average of the countries is 107, Sweden has just under seven percent lower prices than the average.

A price index lower (or higher) than 100 means a theoretical cost increase (saving) that can be achieved if Swedish prices change in relation to foreign prices, provided that Swedish consumption is assumed to be unchanged. This is a strong and unlikely assumption that requires perfectly inelastic demand. If demand is not inelastic, a change in demand will either strengthen or weaken a theoretical cost increase, or saving. The supply of pharmaceuticals, i.e. the entry of competing pharmaceuticals and improvements to existing ones, is also important.

The price index provides a good idea of the price level in comparable countries in relation to Sweden's price level during the period in question. Absolute price index numbers must be interpreted with caution, as they are influenced by both volume and currency effects. This study consistently uses a rolling exchange rate for the past three years. The same applies to the index data reported for 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021 and 2022.

If another country's volume weight is used as a base instead of the volume weight in the country itself, the absolute level of the price index is adjusted, but not necessarily in ranking order between countries.

2.5 Definition of product baskets

To calculate a price index, regardless of whether it is a bilateral or a cross-sectional index, a product basket needs to be defined. A bilateral price index requires that the pharmaceutical is available in Sweden and in the comparison country in order to be included in the price comparison with that country.

The analyses based on cross-sectional indices require that the pharmaceuticals included in the comparison basket are used in at least 40 percent of the countries being compared. In addition, the pharmaceutical must have sales in the base country, which is Sweden in all figures for cross-sections outside the appendices. The product basket forming the base for the cross-sectional index is more limited than the bilateral basket, which is due to the fact that a price for the same basket needs to be determined in all countries. For those countries that do not use a particular pharmaceutical, the European average price is imputed. This average price risks not being representative if the basket is not strictly defined.

To see how different choices of baskets (based on other countries than Sweden) affect the price comparison, information is available in *Appendix 1* in the 2018 report.

2.6 Drivers of relative price

Swedish pharmaceutical prices relative to the rest of Europe are influenced by several different factors. In order to determine which effects have the greatest impact on the relative price level, the total relative price change presented in Sections 3.2.3 and 3.3.4 is divided into effects of price and currency changes, respectively.

The analysis is based on the average price level for pharmaceuticals used in Sweden throughout the period 2014–2022, weighted by the use of each pharmaceutical in 2014. This way, a weighted average price for each year's basket of pharmaceuticals is calculated:

The relative cost of pharmaceutical b at the time t between country i and country j, at the exchange rate $\frac{c_i}{c_j}$ is calculated as:

$$\frac{p_{bit}v_{bit}c_{it}}{p_{bjt}v_{bjt}c_{jt}} = \frac{p_{bit}}{p_{bjt}} \cdot \frac{v_{bit}}{v_{bjt}} \cdot \frac{c_{it}}{c_{jt}}$$

The relative cost change between time point $(t-1)$ and t is then calculated as:

$$\text{Relative cost difference} = \frac{p_{bit}v_{bit}c_{it}}{p_{bjt}v_{bjt}c_{jt}} - \frac{p_{bi(t-1)}v_{bi(t-1)}c_{i(t-1)}}{p_{bj(t-1)}v_{bj(t-1)}c_{j(t-1)}}$$

In the present analysis, Swedish volumes are used throughout to calculate costs in different countries. In that way, the relative *cost* is converted into a relative *price*, weighted according to Swedish use:

$$v_{bjt} = v_{bit} \quad \forall t \in T, \forall b \in B, \forall j \in I \quad \Rightarrow$$

$$\frac{p_{bit}v_{bit}c_{it}}{p_{bjt}v_{bjt}c_{jt}} - \frac{p_{bi(t-1)}v_{bi(t-1)}c_{i(t-1)}}{p_{bj(t-1)}v_{bj(t-1)}c_{j(t-1)}} = \frac{p_{bit}}{p_{bjt}} \cdot \frac{c_{it}}{c_{jt}} - \frac{p_{bi(t-1)}}{p_{bj(t-1)}} \cdot \frac{c_{i(t-1)}}{c_{j(t-1)}}$$

Factoring of price and currency components results in:

$$\begin{aligned} \text{Relative cost difference} = & \frac{p_{bit}}{p_{bjt}} \cdot \frac{c_{it}}{c_{jt}} - \frac{p_{bi(t-1)}}{p_{bj(t-1)}} \cdot \frac{c_{i(t-1)}}{c_{j(t-1)}} \\ = & \left(\frac{p_{bit}}{p_{bjt}} - \frac{p_{bi(t-1)}}{p_{bj(t-1)}}\right)\frac{c_{i(t-1)}}{c_{j(t-1)}} + \quad \text{price component} \\ & \left(\frac{c_{it}}{c_{jt}} - \frac{c_{i(t-1)}}{c_{j(t-1)}}\right)\frac{p_{bit}}{p_{bjt}} \quad \text{currency component} \end{aligned}$$

The above example describes how the relative cost difference is calculated for a particular pharmaceutical $b \in B$. Where B represents a basket of various pharmaceuticals. The total cost difference for the entire basket B at the time t is calculated as a weighted average of all differences, weighted according to the use v_{b2014} for pharmaceutical b in 2014:

$$\overline{Relative\ cost\ difference} = \frac{\sum_{b\in B}\left[\left(\frac{p_{bit}}{p_{bjt}} - \frac{p_{bi(t-1)}}{p_{bj(t-1)}}\right)\frac{c_{i(t-1)}}{c_{j(t-1)}} + \left(\frac{c_{it}}{c_{jt}} - \frac{c_{i(t-1)}}{c_{j(t-1)}}\right)\frac{p_{bit}}{p_{bjt}}\right] v_{b2014}}{\sum_{b\in B} v_{b2014}}$$

2.7 Life cycle analysis

The life cycle figures in Section 3.1 use a different methodology, based on a cross-sectional index. Each country's pharmaceuticals for each year are calculated in relation to the average for that pharmaceutical that year. These relative price levels are then aggregated per pharmaceutical age in the base country only, weighted by sales total. Thus, the input data for the figures only includes the weighted average of the base country's relative price divided by pharmaceutical age.

This means that a pharmaceutical is usually included in several data points, one for each age that pharmaceutical had for the entire period. Note that in doing so, multiple exchange rates are used for the same pharmaceutical. The price of each age is converted at the exchange rate applicable when that pharmaceutical was that age.

2.8 Pharmaceutical classes

Below is a compilation of the defined pharmaceutical classes and which substances fall into each class. The compilation is based on the classification made by the National Board of Health and Welfare in connection with the forecast of pharmaceutical costs. TLV has since revised the classification and mainly categorised more pharmaceuticals.

Table 3. Definition of pharmaceutical classes

Pharmaceutical class	Substances
ADHD	atomoxetine, dexamfetamine, guanfacine, lisdexamfetamine, methylphenidate
Antihistamines	alimemazine, azelastine, fluticasone, budesonide, clemastine, desloratadine, ebastine, emedastine, fluticasone, fluticasone furoate, levocabastine, meclozine, mometasone, olopatadine, phenylpropanolamine, promethazine, promethazine, thiourea
Analgesics	acetylsalicylic acid, caffeine, citric acid, codeine, sodium, acetylsalicylic acid, caffeine, codeine, buprenorphine, buprenorphine, naloxone, codeine, paracetamol, fentanyl, ibuprofen, paracetamol, morphine, naloxone, oxycodone, oxycodone, tapentadol, tramadol
Respiratory system – others	acetylcysteine, aclidinium bromide, aclidinium bromide, formoterol, beclometasone, formoterol, beclometasone, formoterol, glycopyrronium, budesonide, budesonide, formoterol, ciclesonide, dornase alfa, fluticasone, fluticasone furoate, umeclidinium bromide, vilanterol, fluticasone furoate, vilanterol, fluticasone, formoterol, fluticasone, salmeterol, formoterol, formoterol, glycopyrronium, glycopyrronium, glycopyrronium, indacaterol, glycopyrronium, indacaterol, mometasone, indacaterol, indacaterol, mometasone, mometasone, montelukast, olodaterol, olodaterol, tiotropium bromide, salbutamol, salmeterol, terbutaline, tiotropium bromide, umeclidinium bromide, umeclidinium bromide, vilanterol

Pharmaceutical class	Substances
Anemia	darbepoetin alfa, epoetin alfa, epoetin beta, epoetin theta, epoetin zeta, iron ferric, luspatercept, methoxy polyethylene glycol-epoetin beta
Anesthetics	esketamine, fentanyl, lidocaine, lidocaine, prilocaine
Antibiotics and chemo, dermat	fusidic acid, imiquimod, metronidazole, mupirocin, penciclovir
Antidepressants	amitriptyline, bupropion, bupropion, naltrexone, citalopram, clomipramine, duloxetine, escitalopram, fluoxetine, mirtazapine, moclobemide, nortriptyline, paroxetine, reboxetine, sertraline, venlafaxine, vortioxetine
Antiepileptics	brivaracetam, cannabidiol, carbamazepine, clonazepam, eslicarbazepine acetate, felbamate, fenfluramine, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, perampanel, phenobarbital, pregabalin, retigabine, rufinamide, stiripentol, topiramate, valproic acid, vigabatrin, zonisamide
Anti-inflammatory and antirheumatics	penicillin v
Contraceptives	desogestrel, dienogest, estradiol, dienogest, ethinylestradiol, drospirenone, ethinylestradiol, ethinylestradiol, levonorgestrel, etonogestrel, levonorgestrel, medroxyprogesterone, norethisterone
Antiparasitics	Artemether, lumefantrine, atovaquone, chloroquine, clioquinol, flumetasone, hydroxychloroquine, mebendazole, mefloquine, metronidazole, pentamidine, tinidazole
Antipsychotics	aripiprazole, brexpiprazole, cariprazine, chlorprothixene, clozapine, haloperidol, levosulpiride, lurasidone, melperone, olanzapine, paliperidone palmitate, perphenazine, quetiapine, risperidone, sertindole, zuclopenthixol
Cholesterol-lowering	alirocumab, atorvastatin, atorvastatin, ezetimibe, bempedoic acid, bempedoic acid, ezetimibe, bezafibrate, colesevelam, colestipol, colestyramine, evolocumab, ezetimibe, fenofibrate, gemfibrozil, inclisiran, rosuvastatin, simvastatin, volanesorsen
Anticoagulants (excl. NOAC)	caplacizumab, clopidogrel, dalteparin sodium, enoxaparin sodium, epoprostenol, fondaparinux sodium, heparin, iloprost, selexipag, ticagrelor, tinzaparin, treprostinil, warfarin
Antihypertensive drugs	ambrisentan, amlodipine, atenolol, bendroflumethiazide, betaxolol, bisoprolol, bosentan, bumetanide, candesartan cilexetil, candesartan cilexetil, hydrochlorothiazide, diltiazem, doxazosin, enalapril, enalapril, hydrochlorothiazide, eplerenone, eprosartan, eprosartan, hydrochlorothiazide, felodipine, felodipine, metoprolol, furosemide, hydralazine, hydrochlorothiazide, hydrochlorothiazide, losartan, hydrochlorothiazide, quinapril, hydrochlorothiazide, valsartan, irbesartan, lercanidipine, losartan, macitentan, metoprolol, nifedipine, nimodipine, propranolol, ramipril, riociguat, sacubitril, valsartan, spironolactone, tolvaptan, valsartan
CFTR modulators	elexacaftor, ivacaftor, tezacaftor, ivacaftor, ivacaftor, lumacaftor, ivacaftor, tezacaftor
Nervous system – dementia	donepezil, galantamine, memantine, rivastigmine
Diabetes – non insulin	acarbose, alogliptin, canagliflozin, canagliflozin, metformin, dapagliflozin, dapagliflozin, metformin, dapagliflozin, saxagliptin, dulaglutide, empagliflozin, empagliflozin, linagliptin, empagliflozin, metformin, ertugliflozin, ertugliflozin, metformin, ertugliflozin, sitagliptin, exenatide, glibenclamide, linagliptin, linagliptin, metformin, liraglutide, lixisenatide, metformin, metformin, pioglitazone, metformin, saxagliptin, metformin,

Pharmaceutical class	Substances
	sitagliptin, metformin, vildagliptin, saxagliptin, semaglutide, sitagliptin, vildagliptin
Diabetes – insulin and analogs	insulin aspart, insulin aspart, insulin aspart protamine, insulin aspart, insulin aspart protamine crystalline, insulin degludec, insulin degludec, liraglutide, insulin detemir, insulin glargine, insulin glargine, lixisenatide, insulin glulisine, insulin human base, insulin human base, insulin human isophane, insulin human isophane, insulin lispro, insulin lispro, insulin lispro protamine
Endocrine therapy	abiraterone acetate, anastrozole, apalutamide, bicalutamide, buserelin, darolutamide, degarelix, enzalutamide, fulvestrant, goserelin, letrozole, leuprorelin, medroxyprogesterone, tamoxifen, toremifene, triptorelin
Gynaecological agents	bromocriptine, clindamycin, metronidazole, quinagolide
Haematology – others	berotralstat, betibeglogene autotemcel, c1 inhibitor (human), conestat alfa, crizanlizumab, fostamatinib, icatibant, lanadelumab, tranexamic acid
Hepatitis C	dasabuvir, elbasvir, grazoprevir, glecaprevir, pibrentasvir, ledipasvir, sofosbuvir, ombitasvir, paritaprevir, ritonavir, ribavirin, sofosbuvir, sofosbuvir, velpatasvir, sofosbuvir, velpatasvir, voxilaprevir
HIV	abacavir, abacavir, dolutegravir, lamivudine, abacavir, lamivudine, abacavir, lamivudine, zidovudine, atazanavir, cobicistat, bictegravir, emtricitabine, tenofovir alafenamide, cabotegravir, cobicistat, darunavir, cobicistat, darunavir, emtricitabine, tenofovir alafenamide, cobicistat, elvitegravir, emtricitabine, tenofovir alafenamide, dolutegravir, dolutegravir, lamivudine, dolutegravir, rilpivirine, doravirine, doravirine, lamivudine, tenofovir disoproxil, emtricitabine, emtricitabine, rilpivirine, tenofovir alafenamide, emtricitabine, rilpivirine, tenofovir disoproxil, emtricitabine, tenofovir alafenamide, emtricitabine, tenofovir disoproxil, etravirine, lamivudine, letermovir, raltegravir, rilpivirine, tenofovir alafenamide, tenofovir disoproxil, zidovudine
Cardiac therapy	alprostadil, amiodarone, angiotensin 2 (human), dronedarone, etilefrine, flecainide, ibuprofen, paracetamol, isosorbide mononitrate, lidocaine, lidocaine, methylprednisolone, mexiletine, midodrine, nitroglycerin, propafenone, ranolazine
Dermatology drugs – others	adapalene, adapalene, benzoyl peroxide, afamelanotide, alitretinoin, azelaic acid, betamethasone, calcipotriol, brimonidine, brimonidine, brinzolamide, clindamycin, clindamycin, tretinoin, diclofenac, econazole, econazole, triamcinolone acetonide, finasteride, hydrocortisone, miconazole, isotretinoin, ivermectin, lidocaine, pimecrolimus, tacrolimus
Immunoglobulins	bezlotoxumab
Immunostimulatory	filgrastim, interferon beta-1a, interferon beta-1b, lenograstim, lipegfilgrastim, pegfilgrastim, peginterferon alfa-2a, peginterferon beta-1a, ropeginterferon alfa 2b
Immunosuppressive – others	azathioprine, canakinumab, ciclosporin, darvadstrocel, dimethyl fumarate, eculizumab, lenalidomide, methotrexate, mycophenolate mofetil, mycophenolic acid, ozanimod, pirfenidone, pomalidomide, ravulizumab, siltuximab, sirolimus, tacrolimus, thalidomide, tildrakizumab
Incontinence	darifenacin, fesoterodine, mirabegron, oxybutynin, tolterodine
Blood coagulation factors	albutrepenonacog alfa, avatrombopag, damoctocog alfa pegol, efmoroctocog alfa, eftrenonacog alfa, eltrombopag,

Pharmaceutical class	Substances
	emicizumab, eptacog alfa (activated), factor x, lonoctocog alfa, lusutrombopag, moroctocog alfa, nonacog alfa, nonacog beta pegol, nonacog gamma, octocog alfa, romiplostim, rurioctocog alfa pegol, simoctocog alfa, susoctocog alfa, turoctocog alfa, turoctocog alfa pegol
Corticosteroids, dermat.	betamethasone, betamethasone, calcipotriol, betamethasone, clioquinol, betamethasone, salicylic acid, clobetasol, clobetasone, fluticasone, fusidic acid, hydrocortisone, hydrocortisone, hydrocortisone, oxytetracycline, mometasone
Sex hormones – oestrogen	conjugated, bazedoxifene, estrogenic substances, estradiol, estradiol, medroxyprogesterone, estradiol, norethisterone, ethinylestradiol, levonorgestrel, medroxyprogesterone, norethisterone, progesterone
Sex hormones – others	choriogonadotropin alfa, corifollitropin alfa, cyproterone, follitropin alfa, follitropin beta, follitropin delta, ospemifene, testosterone, ulipristal acetate, urofollitropin
Migraine drugs	dihydroergotamine, dihydroergotamine, etilefrine, erenumab, fremanezumab, galcanezumab, rizatriptan, sumatriptan, zolmitriptan
MS	cladribine, fampridine, fingolimod, glatiramer acetate, interferon beta-1a, interferon beta-1b, natalizumab, ocrelizumab, ofatumumab, peginterferon beta-1a, siponimod, teriflunomide
Muscle relaxant	caffeine, orphenadrine, propyphenazone, chlorzoxazone, orphenadrine, paracetamol
Musculoskeletal drugs – others	allopurinol, ataluren, chondrocyte, febuxostat, nusinersen, onasemnogene abeparvovec, risdiplam
Nervous system – others	acamprosate, ambenonium, cinnarizine, dimenhydrinate, disulfiram, idebenone, inotersen, modafinil, patisiran, pilocarpine, piracetam, pitolisant, pyridostigmine, solriamfetol, tafamidis, varenicline
NOAC	apixaban, dabigatran etexilate, edoxaban, rivaroxaban
NSAID	benzydamine, dexibuprofen, diclofenac, diclofenac, misoprostol, etoricoxib, ketoprofen, nabumetone, naproxen, phenylbutyrate, piroxicam betadex, tenoxicam
Oncology – protein kinase inhibitors	abemaciclib, acalabrutinib, afatinib, alectinib, alpelisib, axitinib, binimetinib, bosutinib, brigatinib, cabozantinib, ceritinib, crizotinib, dabrafenib, dacomitinib, dasatinib, encorafenib, entrectinib, erlotinib, everolimus, gefitinib, gilteritinib, ibrutinib, idelalisib, imatinib, lapatinib, larotrectinib, lenvatinib, lorlatinib, midostaurin, neratinib, nilotinib, nintedanib, osimertinib, palbociclib, pazopanib, ponatinib, regorafenib, ribociclib, ruxolitinib, sorafenib, sunitinib, tivozanib, trametinib, vandetanib, vemurafenib
Oncology – others	aflibercept, aminolevulinic acid, anagrelide, asparaginase, asparaginase escherichia coli, atezolizumab, avapritinib, avelumab, axicabtagene ciloleucel, belantamab mafodotin, bexarotene, blinatumomab, brentuximab vedotin, busulfan, cabazitaxel, capecitabine, carboplatin, carfilzomib, cemiplimab, chlorambucil, chlormethine, cobimetinib, cytarabine, cytarabine, daunorubicin, daratumumab, durvalumab, elotuzumab, epirubicin, eribulin, estramustine, etoposide, fludarabine, fluorouracil, fluorouracil, salicylic acid, gemtuzumab ozogamicin, gimeracil, oteracil, tegafur, glasdegib, idarubicin, inotuzumab ozogamicin, ipilimumab, isatuximab, ixazomib, melphalan, mercaptopurine, methotrexate, methyl-5-aminolevulinic acid, mitotane, mogamulizumab, necitumumab, niraparib, nivolumab,

Pharmaceutical class	Substances
	obinutuzumab, olaparib, paclitaxel, padeliporfin, panitumumab, panobinostat, pegaspargase, pembrolizumab, pertuzumab, pertuzumab, trastuzumab, polatuzumab vedotin, ramucirumab, rituximab, rucaparib, sonidegib, talazoparib, talimogene laherparepvec, temozolomide, tioguanine, tipiracil, trifluridine, tisagenlecleucel, topotecan, trabectedin, trastuzumab, trastuzumab deruxtecan, trastuzumab emtansine, treosulfan, venetoclax, vinorelbine, vismodegib
Opioid addiction	buprenorphine, buprenorphine, naloxone, levomethadone, methadone
Osteoporosis	alendronic acid, alendronic acid, calcium, colecalciferol, burosumab, clodronic acid, denosumab, dibotermin alfa, pamidronic acid, risedronic acid, romosozumab, teriparatide
Parkinson	apomorphine, benserazide, levodopa, biperiden, bromocriptine, carbidopa, entacapone, levodopa, carbidopa, levodopa, opicapone, pramipexole, ropinirole, rotigotine, safinamide, selegiline, tolcapone
Thyroid disease	levothyroxine sodium, thiamazole
Systemic antibacterials	amoxicillin, ampicillin, avibactam, ceftazidime, aztreonam, ceftazidime, ceftolozane, tazobactam, ceftriaxone, ciprofloxacin, ciprofloxacin, fluocinolone acetonide, clindamycin, colistin, dalbavancin, delafloxacin, flucloxacillin, fusidic acid, levofloxacin, linezolid, lymecycline, mecillinam, meropenem, vaborbactam, methenamine, nitrofurantoin, norfloxacin, oritavancin, penicillin v, pivmecillinam, tedizolid, teicoplanin, tobramycin
Systemic antiviral drugs – others	adefovir dipivoxil, amphotericin b, bedaquiline, cefiderocol, cilastatin, imipenem, relebactam, delamanid, entecavir, eravacycline, ethambutol, famciclovir, fluconazole, ibalizumab, isavuconazole, isavuconazonium, isoniazid, posaconazole, rifabutin, rifampicin, valaciclovir, valganciclovir, voriconazole, zanamivir
Systemic anti-virals	bulevirtide, remdesivir
Systemic hormone therapy – others	betamethasone, cetrorelix, cinacalcet, desmopressin, dexamethasone, etelcalcetide, fludrocortisone, ganirelix, hydrocortisone, ketoconazole, lanreotide, lidocaine, methylprednisolone, mecasermin, nafarelin, octreotide, osilodrostat, parathyroid hormone, paricalcitol, pasireotide, pegvisomant, prednisolone, somatropin
Anxiolytics and sedatives	buspirone, clomethiazole, diazepam, hydroxyzine, melatonin, midazolam, nitrazepam, oxazepam, propiomazine, tasimelteon, zolpidem, zopiclone
Selected biological, anti-inflammatory compounds	abatacept, anakinra, apremilast, baricitinib, belimumab, benralizumab, bimekizumab, brodalumab, dupilumab, filgotinib, guselkumab, ixekizumab, mepolizumab, omalizumab, reslizumab, risankizumab, sarilumab, secukinumab, tocilizumab, tofacitinib, upadacitinib, ustekinumab, vedolizumab
Selected biological, TNF-inhibitors	adalimumab, certolizumab pegol, etanercept, golimumab, infliximab
Urologicals	alfuzosin, alprostadil, aviptadil, phentolamine, finasteride, sildenafil, tadalafil, terazosin
Alimentary tract	agalsidase alfa, agalsidase beta, amphotericin b, asfotase alfa, balsalazide, benzydamine, bisacodyl, budesonide, budesonide, formoterol, carglumic acid, cerliponase alfa, chenodeoxycholic acid, domperidone, eliglustat, elosulfase alfa, eluxadoline, esomeprazole, fidaxomicin, fosnetupitant, palonosetron, galsulfase, givosiran, glycerol phenylbutyrate, glycopyrronium,

Pharmaceutical class	Substances
	granisetron, hydrocortisone, lansoprazole, laronidase, linaclotide, loperamide, lumasiran, mercaptamine, mesalazine, methylnaltrexone bromide, migalastat, miglustat, misoprostol, morphine, naldemedine, naloxegol, netupitant, palonosetron, nitisinone, nystatin, obeticholic acid, olsalazine, omeprazole, ondansetron, orlistat, pantoprazole, pegvaliase, phenylbutyrate, prasterone, prednisolone, prucalopride, racecadotril, rifaximin, sapropterin, sebelipase alfa, sulfasalazine, teduglutide, telotristat etiprate, trientine, vancomycin, velaglucerase alfa, velmanase alfa, vestronidase alfa
Ophthalmologicals	acetazolamide, apraclonidine, betaxolol, bimatoprost, bimatoprost, timolol, brimonidine, brinzolamide, brimonidine, timolol, brinzolamide, brinzolamide, timolol, brolucizumab, cenegermin, ciclosporin, ciprofloxacin, dexamethasone, diclofenac, dorzolamide, dorzolamide, timolol, fusidic acid, hydrocortisone, latanoprost, latanoprost, timolol, nepafenac, pilocarpine, prednisolone, ranibizumab, tafluprost, tafluprost, timolol, timolol, timolol, travoprost, tobramycin, travoprost, verteporfin, voretigene neparvovec
Otologicals	ciprofloxacin, ciprofloxacin, fluocinolone acetonide, clioquinol, flumetasone, hydrocortisone, oxytetracycline, polymyxin b
Others	autologous limbal stem cells, brexucabtagene autoleucel, deferasirox, deferiprone, deferoxamine, inhaler device, na, naloxone, naloxone, oxycodone, patiromer calcium, polystyrene sulfonate, sevelamer, sucroferric oxyhydroxide, sugammadex, zirconium cyclosilicate, budesonide, formoterol, glycopyrronium, filgotinib