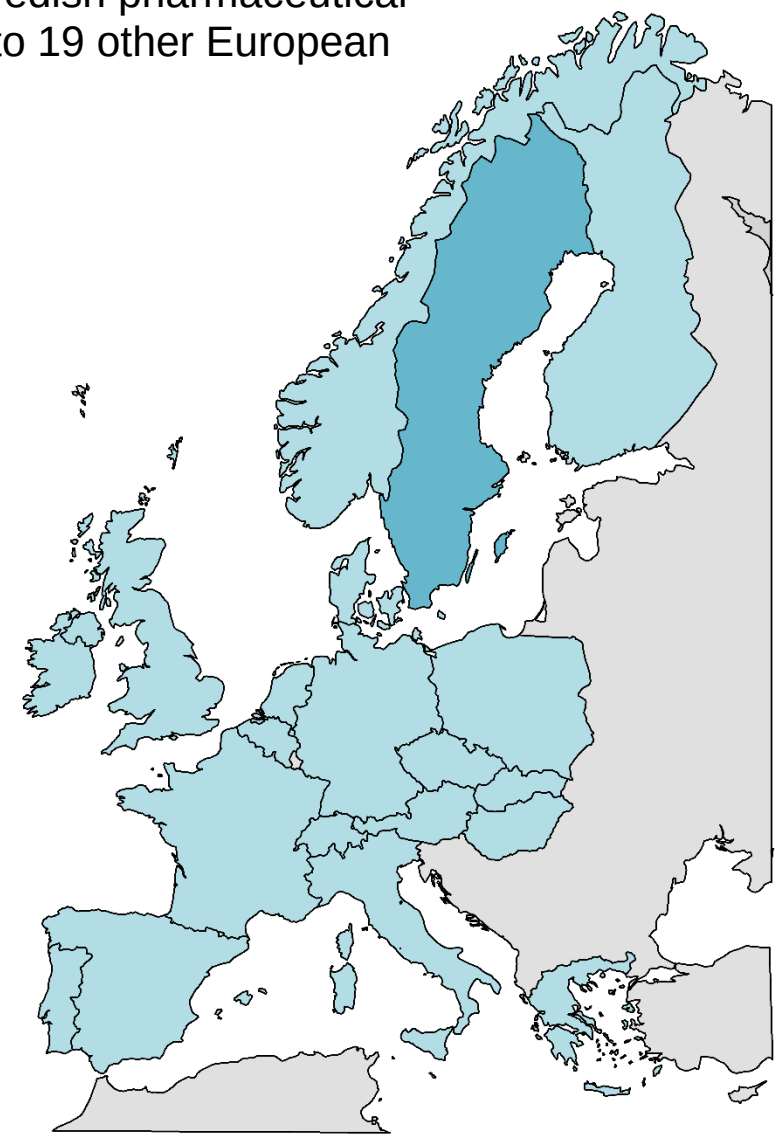
International price comparison 2020

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) shall, according to its' mandate, monitor and analyse the pharmaceutical price development 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 2020 in Sweden in comparison with 19 other European countries. The analysed segments are pharmaceuticals without competition and pharmaceuticals with competition. Pharmaceuticals with competition include pharmaceuticals available as substitutable pharmaceuticals in the product-of-the-month system as per March 2020.

The working group for the report included David Sjöberg, Oskar Johansson, Daniel Högberg, and Per Hortlund. This year, extra focus has been on analysing why Sweden's relative price level for pharmaceuticals is higher when the pharmaceuticals have been on the market for a few years. In addition, descriptions of other countries have been updated which enable comparisons from other countries' perspectives so that more people can make use of the results of the report.

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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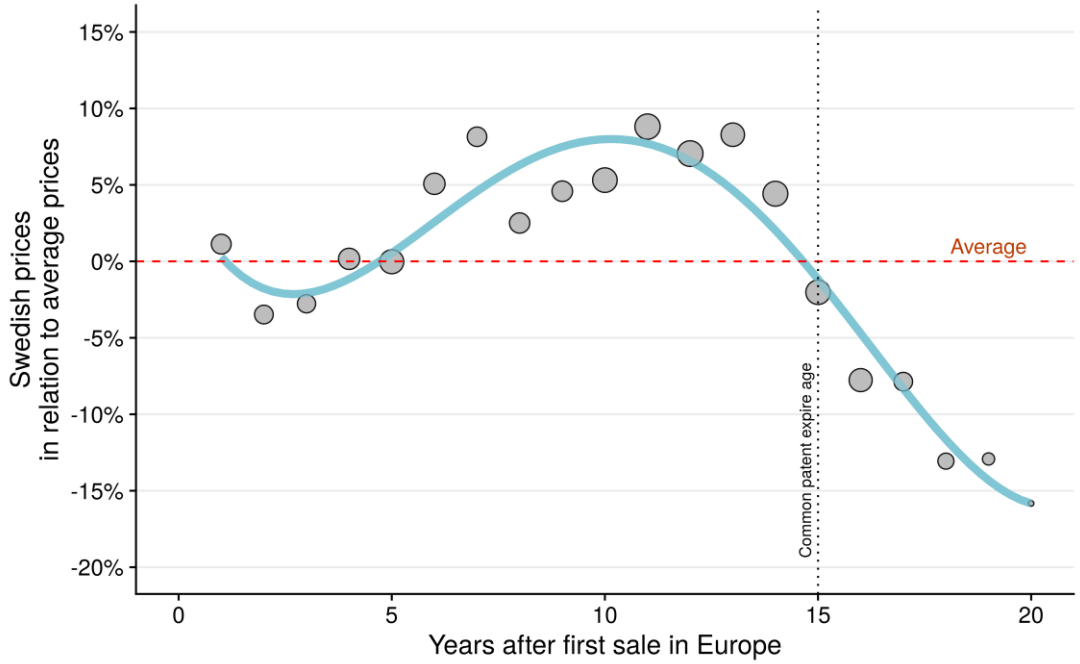
Summary

This report is part of TLV's mandate to analyse developments in the Swedish pharmaceutical market from an international perspective. The report is the seventh annual report of its kind. The report analyses Swedish prices over the pharmaceutical life cycle. The analysis compares the price level of pharmaceuticals used in Swedish outpatient care with 19 other European countries. The analysis is based on national pharmacy wholesale list prices. In several countries, there are agreements on discounts or repayments, meaning that the net cost of pharmaceuticals will ultimately be lower than the cost based on officially determined list prices.

In Sweden, *value-based pricing* is used for pharmaceuticals without generic competition. This means that pharmaceuticals are compared with other treatment alternatives in Sweden in terms of effect and price. In Europe, however, it is more common to use another pricing model, *international reference pricing,* where other countries' prices are also used as a basis. This year, the report includes an updated description of price and subsidy systems in other countries, see appendix.

In general, Swedish prices have fallen in relation to prices in other European countries. The prices of new pharmaceuticals in Sweden are in line with, or slightly lower than, other countries at the time the pharmaceutical was put on the market. During the period when pharmaceuticals are between 5 and 15 years from the first sale in Europe, Sweden's prices gradually increase compared to the average. For pharmaceuticals subjected to competition through the Product-of-the-month system, Sweden has the lowest prices among the countries included in the comparison. The falling relative prices have been a trend since 2016, primarily as a result of the Swedish krona weakening in relation to the Euro.

Sweden's relative pharmaceutical prices in 2014–2020 compared with the average price for the report's 20 European countries. The comparison is made per year after first sale in Europe.



Source: IQVIA and TLV analysis.
Note 1: The red line shows the average prices for 20 European countries. The position of the circles shows the actual deviation from the average prices, and their size shows how large the sales value is in Sweden for pharmaceuticals of that age. The blue line is an approximate calculation to show the trend over the life cycle. Sales data for the years 2014–2020.
Note 2: The figure should be interpreted as Sweden's average relative price per pharmaceutical age for all years 2014–2020. Thus, it only tells us Sweden's relative price level for the entire period.

For *pharmaceuticals without generic competition*, i.e. pharmaceuticals not included in the Swedish generic substitution system (product-of-the month system), Sweden takes sixth place out of 20 countries in 2020 in a bilateral comparison where the country in first place has the lowest price. The placement is a move from ninth place in 2019 thanks to a relative price reduction of around 3.4 percentage points. The relative price reduction is mainly a result of exchange rate fluctuations. The falling Swedish krona has contributed to pharmaceutical areas that previously had high relative prices in Sweden in comparison with the rest of Europe now being at a similar or lower level than the European average price. If the exchange rate stayed at the 2014 level, Sweden would take 14th place in 2020.

For some pharmaceuticals, however, net costs are lower as a result of managed entry agreements generating repayments from the pharmaceutical companies to the regions and to the state in Sweden. Cost reductions due to repayments are not visible in the comparison of public list prices. For pharmaceuticals without generic competition, spontaneous price competition between pharmaceuticals with comparable or equivalent effect rarely arises on the Swedish market. The prices for these pharmaceuticals usually stay at the same level until the pharmaceuticals are either covered by the 15-year rule or the product-of-the-month system or an intervention from TLV or the regions. Historically, TLV's reviews of price and reimbursement status in 2014–2017 led to significant price reductions and savings

in benefits. From 2016, the regions have also, in connection with price change applications or reviews initiated by TLV, signed managed entry agreements with the companies on repayments for several pharmaceuticals, which has contributed to reduced costs both through direct rebates and through reductions in fixed prices.

For *pharmaceuticals with competition*, i.e. pharmaceuticals included in the Product-of-the-month system, Sweden has the lowest prices in comparison with the other countries in the comparison. The competition in the Product-of-the-month system is an effective way to take advantage of a natural competition between substitutable pharmaceuticals. In the Product-of-the-month system, pharmaceutical companies can raise prices up to a ceiling price, meaning that prices in Swedish kronor can be raised if the Swedish krona weakens.

For pharmaceuticals within the Product-of-the-month system, prescribers, patients, or dispensing pharmacists may refuse generic substitutes at the pharmacy. In areas where a higher proportion of prescribers and/or patients refuse substitutes, competition tends not to lead to as intense price pressure as in areas where a higher proportion is substituted at the pharmacy.

There are several areas where there is no natural price competition even though there may be generic alternatives to original products or that there are several original products with a comparable effect. For the years 2014–2017, TLV was commissioned by the government to reduce the costs of preferential pharmaceuticals by SEK 1,175 million. During these years, the costs for pharmaceuticals already included in the benefits were reduced by SEK 1,192 million, of which SEK 623 million were price reductions in connection with reconsiderations. This led to Swedish prices falling in relation to other countries. From 2016, reviews of reimbursement status have been made while regions and companies have signed managed entry agreements on repayments on pharmaceuticals already included in benefits. This has, in combination with reductions in the wholesale price (PRP), led to reduced social costs for preferential pharmaceuticals. More than half of the more than three billion paid in repayments in 2019 comes from older pharmaceuticals, which previously existed within the benefit without a managed entry agreement. Discounts and repayments, which are becoming more common in many countries, are often not public, making it impossible to compare real costs between countries for these products. The sales value (PRP), for pharmaceuticals covered by managed entry agreements constitutes around 18 percent of the costs for preferential pharmaceuticals, i.e. a smaller section of the Swedish pharmaceutical market. This report is therefore an important basis for describing and analysing the Swedish pharmaceutical market.

Terms and concepts

ATC - *Anatomical Therapeutic Chemical (ATC) classification system* 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 Hormonal preparations excluding sex hormones
J Infectious diseases
L Tumours and immune system disorders
M Musculoskeletal system
N Nervous system
P Antiparasitic products, insecticides, and repellents
R Respiratory system
S Sensory organs
V Various

Active substance - the substance in a pharmaceutical product that gives it its medical effect.

Bilateral price index – price index describing the relative price between two countries. The same product needs to be available in both countries to be included in the bilateral price index.

Branded 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.

Ceiling prices in substitutable pharmaceutical groups – in the Swedish product-of-the-month system, the maximum accepted price (wholesale price per unit) of a pharmaceutical in a package size group. The price per unit for any packaging in the substitution group must have fallen below 30 percent of the price which was the highest price in its packaging size group when generic competition arose.

Cross-sectional price index - price index describing relative prices in more than two countries. The same product needs to be available in several countries to be included in any of the countries' price indices. The threshold, so-called 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, Swedish prices are used instead.

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

ERP – External Reference Price - Pricing method where 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.

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 containing the same active substance as an original product, in the same dosage form, and with the same strength, and which give the same effect.

INN - Generic name - like the chemical name, describes a substance. Generic names are established by several different countries and by the WHO.

List price - Price paid without regard to discounts or repayments. Corresponds in this report to fixed prices at wholesale price (AIP in Sweden). When countries, including Sweden, are referred to as a group, the term list prices are used to describe the wholesale price in Sweden.

Managed entry agreement - collective name of an agreement that means that the cost of using the pharmaceutical is reduced, such as risk-sharing agreements, discount and repayment agreements. In Sweden, these agreements are concluded between the pharmaceutical companies and the regions.

Managed introduction - In Sweden called *National managed introduction of new drug therapies*. Sweden's regions are collaborating on which new pharmaceutical therapies to introduce in healthcare. The national managed introduction is coordinated by the New Therapies (NT) Council.

Pharmaceutical benefits - a pharmaceutical included in the pharmaceutical benefits scheme is subsidised and included in the high-cost protection system.

Product - a pharmaceutical with the same substance, dosage form, and strength

PRP - Pharmacy retail price (in Sweden AUP) - the pharmacy sales price in SEK. In Sweden determined by TLV.

Product-of-the-month – In Sweden, products-of-the-month are the 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. PV-system in Swedish.

PWP - Pharmacy wholesale price - the pharmacy wholesale price in SEK. In Sweden determined by TLV.

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. Relative prices may also be affected by the currency exchange rate.

Repayment - a form of compensation 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 from a managed entry agreement.

Risk-sharing agreements - agreements where 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.

Pharmaceuticals with competition - includes all pharmaceuticals in Sweden included in the product-of-the-month list as per March 2020.

Pharmaceuticals without competition - includes products where 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.

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

1 Introduction

1.1 Assignment

TLV has a mandate to monitor and analyse the developments in the pharmaceutical, pharmacy and dental care markets. One of TLV's assignments is to develop value-based pricing to ensure that pharmaceuticals costs are reasonable throughout their entire life cycle. Part of this work involves looking at Sweden's pharmaceutical prices and usage from an international perspective. 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 developments in the sector from an international perspective.

The comparison includes pharmaceuticals without competition as well as pharmaceuticals with competition. The report describes how the prices of prescription medicines in Sweden compare with 19 other countries in Europe. For all countries included in the comparison, see Table 1 below.

Chart 1. Countries included in the analysis

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

The purpose is to analyse how Swedish pharmaceutical prices compare in an international perspective. We also examine the dynamics in terms of prices, volumes, and exchange rates and how they have affected Sweden's relative price level.

1.1.1 Delimitation and definitions

The assignment does not include determining whether Swedish pharmaceutical prices are at the desired level, nor how to design potential changes to reach such level. This report mainly analyses the outpatient care market. Thus, pharmaceuticals handled in inpatient care are given limited space. The proportion of pharmaceuticals dispatched within inpatient and outpatient care varies greatly between countries.

In Sweden, price and cost analyses are based on official prices (pharmacy wholesale price, PWP)[1]. The statistics analysed in the report are based on other countries' list prices (PWP), meaning that the starting point for the analyses in this report is list prices. In Sweden, list prices consist of the prices determined by TLV (in this report AIP).

In Sweden, there are agreements between regions and pharmaceutical companies, so-called managed entry agreements, which involve repayment of parts of the pharmaceutical costs. Thus, pharmaceutical costs are affected by repayments due to managed entry agreements. That effect is not captured in this report, as the analysis focuses on price development over time. Thus, a comparison of price differences remains relevant.

The report generally uses exchange rates calculated as a three-year moving average. This is done so as not to overestimate the effect of exchange rate changes, while at the same time giving a fair presentation of how prices vary between Sweden and other countries, see further in section 1.1 in Appendix 1. The prices used are prices for the first quarter each year during the time period and the volume weighting is rolling 12 months from the first quarter each year.

1.2 Outline

Under the heading *Methodology and data,* 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 is divided into three sections. First, an in-depth study of the pharmaceutical life cycle, where prices are analysed based on the pharmaceutical age. Then, a more detailed description of pharmaceuticals without competition (outside the product-of-the-month system), followed by pharmaceuticals with competition, within the product-of-the-month system.

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

The report has two appendices. A more comprehensive description of the methodology, sensitivity analyses, and previous studies can be found in *Appendix 1: Sensitivity analysis and methodology*. In *Appendix 2 Price and subsidy systems* in Europe*,* there are detailed descriptions of all countries' systems, which provides additional knowledge on differences and similarities between countries and price systems.

[1] or official prices for PRP (pharmacy retail price)

1.3 Methodology and data

1.3.1 Description of data sources

Methodology and data selection are briefly described here. A more in-depth account can be found in the chapter *Methodology* in *Appendix 1*.

TLV has used price and sales data from the consulting company IQVIA for the first quarters of the years 2014 to 2020. The price level in Sweden is compared with 19 other European countries.

The selection consists of prescription medicines for human use, in Sweden 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 innovative substances[2]. By complementing the selection with European bestsellers, the comparison becomes fairer, as more relevant pharmaceuticals are compared. A total of 951 substances and 11,663 pharmaceuticals are included in the analysis[3]. The market has been divided into pharmaceuticals without and with competition. Competition means that the pharmaceuticals have generic competition and are substitutable in Swedish pharmacies. This means that the pharmaceutical is included in the Swedish product-of-the-month system, meaning that the pharmaceutical is substitutable at pharmacies in Sweden. Divided in accordance with this definition, 2020 includes[4]:

- **Pharmaceuticals without competition**
  882 substances and 6,042 pharmaceuticals.
- **Pharmaceuticals with competition**
  241 substances and 616 pharmaceuticals

In Sweden, pharmaceuticals without competition during Q1 2020 accounted for approximately 81 percent of the sales volume (wholesale price; AIP) and pharmaceuticals with competition for approximately 19 percent. IQVIA's data covers around 90 percent of sales in Sweden in 2020. The price comparison is based on prices in other countries and in Sweden. In Sweden, prices are fixed in the form of the pharmacy wholesale price (AIP), but in comparison with other countries, Sweden's prices are also referred to as list prices. Discounts on list prices and repayments as a result of managed entry agreements are not included in the input data. A substitutable pharmaceutical is defined as a pharmaceutical with the same substance, dosage form, and strength. The price is calculated as cost per unit[5].

1.3.2 Method

One challenge with price comparisons between countries is that not all countries use the same pharmaceuticals as in Sweden. The proportion of the same pharmaceutical used in two countries that are compared is called matching rate. The report uses three methods to compare prices. The methods are partly similar

[2] EFPIA's WAIT Indicator. https://www.efpia.eu/media/412747/efpia-patient-wait-indicator-study-2018-results-030419.pdf (2019-11-10)
[3] Pharmaceuticals are defined as a combination of substance, dosage form, and strength.
[4] A substance can be found in both the pharmaceuticals segment with and without competition. This is because different forms and strengths of the same substance can have different competitive status.
[5] According to IQVIA's definition of sales volumes in counting units

but differ in how they handle differences in which pharmaceuticals are used and not used in the different countries:

- **Bilateral comparison**
  Compares prices *only* for those pharmaceuticals available in an individual country and in Sweden. If, for example, Finland uses 59 percent of the pharmaceuticals used in Sweden, the price comparison only covers 59 percent of the pharmaceuticals in Sweden. Pharmaceuticals with very low sales in relation to the base country's local market have been excluded.

- **Bilateral average**
  The same methodology as bilateral comparison, but the analysis is carried out once per country with each country's pharmaceutical use. Then an average is calculated for each country. Sweden's relative price level will then be the average level calculated over bilateral comparisons for all countries' 'price baskets', i.e. the pharmaceuticals a country uses. The bilateral comparison described above 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. By comparing all countries' pharmaceutical use as a methodology, a more trans-European ranking between countries is achieved.

- **Cross-sectional comparison**
  Assumes that *all* countries in the study have *all* 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 sold in at least eight countries to be included in the cross-sectional comparison.

The cross-section analysis is used to calculate the development of Swedish prices in relation to the European average. The bilateral price comparison describes price differences between individual countries and Sweden. Both the bilateral and cross-section price comparison 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 section 2 in Appendix 1.

2 Overview of the pharmaceutical market

The purpose of the sections on market overview and facts about the countries in the study is to provide a background to the context in which the results of the international price comparison for pharmaceuticals should be viewed. Some of the countries in the study have major similarities in their healthcare systems and systems for pricing pharmaceuticals, while others are more diverse. This may relate to transparency regarding list prices and whether or not discount systems are institutionalised and included in pharmacy purchase prices, or if other agreements mean that certain list prices do not fully reflect the actual price of a pharmaceutical.

Globally, pharmaceuticals had sales of around SEK 8,672 billion in 2019, calculated as the price from the manufacturer. North America dominates the pharmaceutical market and accounts for about 49 percent of the world market. Europe accounts for about 23 percent. Africa, Asia, and Australia combined account for about 17 percent, Japan just over 7.4 percent, and Latin America just over 3 percent.[6]

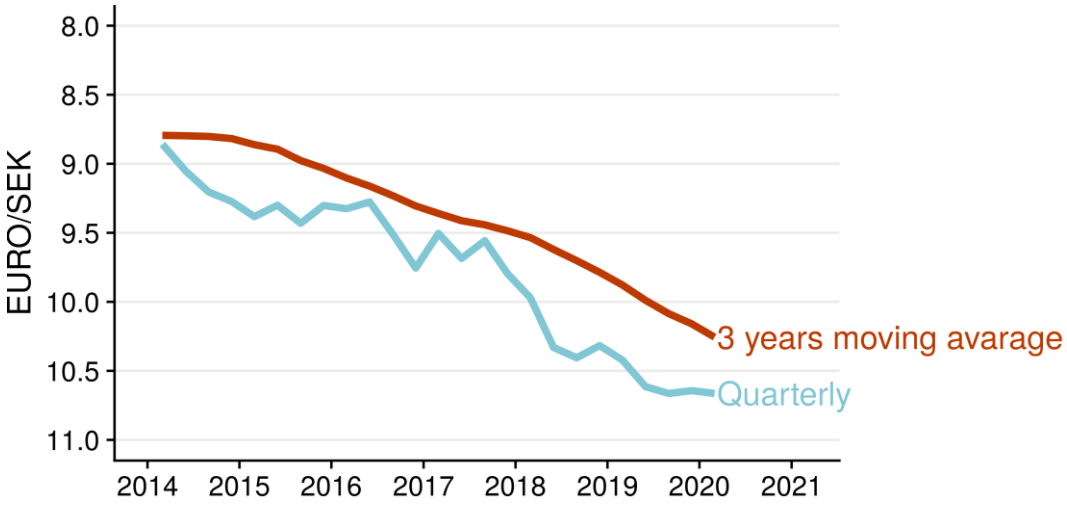
2.1 Currency exchange rate

The development of the Swedish krona has been weak in recent years and continues in the same direction until the first quarter of 2020. To get a more balanced picture of Swedish relative prices, exchange rates have therefore been calculated as a three-year moving average.

The diagram below shows the development of the Swedish krona quarterly and as a three-year moving average to clarify the difference depending on the method used.

[6] EFPIA, The Pharmaceutical Industry in Figures 2019, states that global sales amount to 845,235 million euros. Calculation to SEK according to the average exchange rate (10.26) in 2018.
EFPIA (2019) The Pharmaceutical Industry in Figures, Key data 2019.
https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf

Figure 1. Development of the Swedish krona, quarterly and in 3-year moving average, 2014–2020



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

The weakening of the Swedish krona against the Euro means that pharmaceuticals with an unchanged fixed price in Swedish kronor will be less expensive in Euros. To avoid the analyses being affected by temporary exchange rate fluctuations, an average exchange rate over a moving three-year period is used. This exchange rate is not affected by temporary changes, while at the same time taking into account more long-term effects.

In some figures, a *fixed exchange rate* is used. It may be that the 2014 exchange rates are used for prices in all years between 2014–2020. Fixing the exchange rate better describes what different countries see for price changes in local currency and reflects whether there is a price dynamic in addition to exchange rates. See section 1.1 in Appendix 1 for more information. The sensitivity analysis also tests the outcome at other exchange rates.

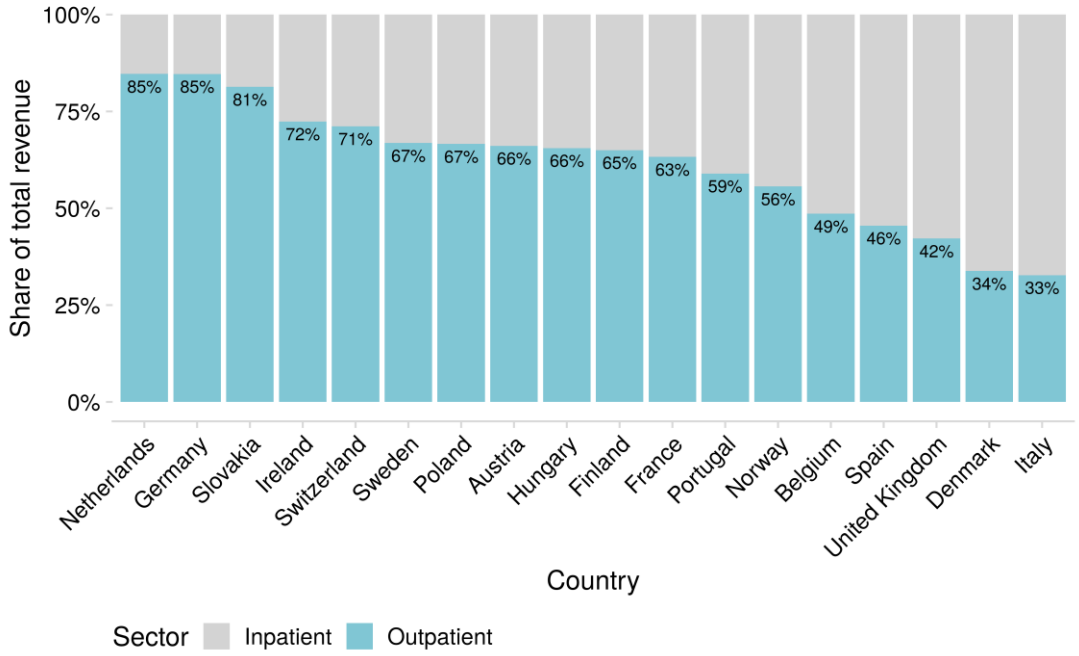
2.2 Outpatient and inpatient care

The analyses in this report are mainly based on pharmaceutical prices in outpatient care, meaning that the pharmaceuticals are collected at a pharmacy. In some countries, some pharmaceuticals are mainly managed within inpatient care, while the same pharmaceuticals are prescribed in outpatient care in Sweden. Comparisons that only include data from outpatient care must be made with some caution. Choices on the management of pharmaceuticals –prescriptions in outpatient care or in hospitals within inpatient care – complicate this type of comparison if you lack knowledge of specific national conditions.

The following figure shows the percentage of pharmaceutical management within outpatient and inpatient care by sales value. On average, these 19 countries manage just over 61 percent of total sales within outpatient care. Denmark, Italy, the United Kingdom, and Spain have a relatively low sales value within outpatient care, while a significantly higher proportion is managed within inpatient care. In Sweden, around

two-thirds are managed through prescriptions in outpatient care and around one-third are handled within the scope of inpatient care.

Figure 2. Percentage of sales value in wholesale price within inpatient care and outpatient care, respectively, per country



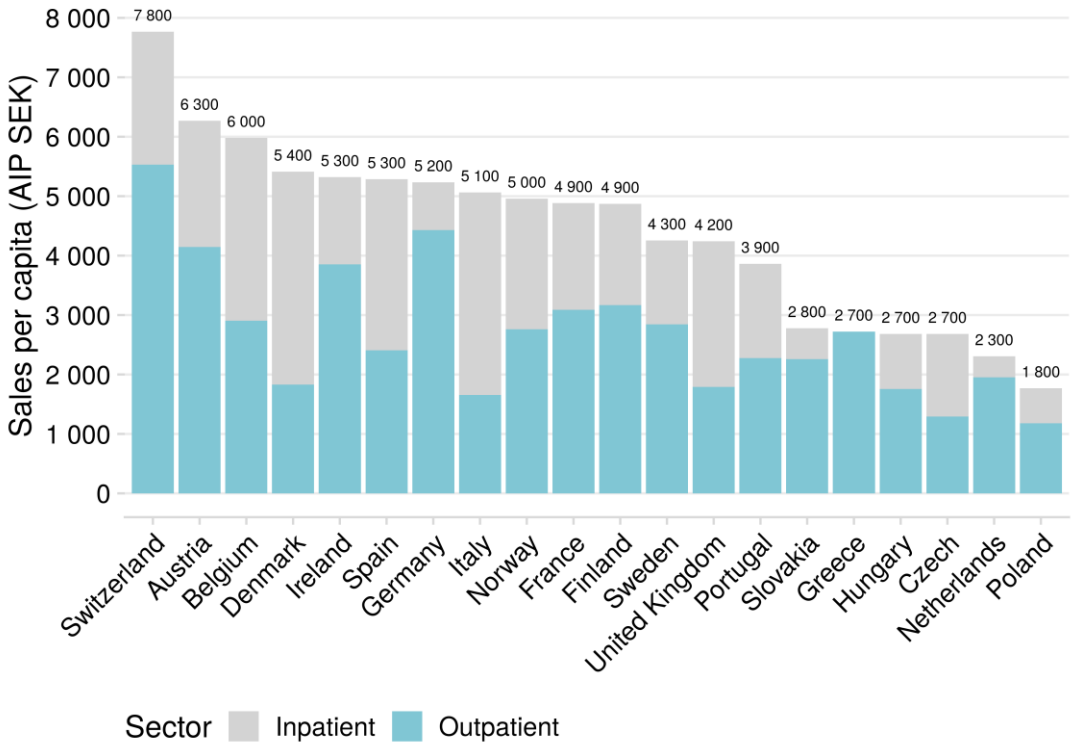
Source: IQVIA and TLV analysis.
Note: Data applies to March 2020, rolling 12 months. Greece is excluded as there is no available information on inpatient care.

In the 2019 report, the proportion of outpatient pharmaceuticals in Sweden was 75 percent, but the figure above shows that the corresponding proportion in 2020 is 67 percent. The big difference is mainly due to the fact that IQVIA no longer has access to data on inpatient care use of pharmaceuticals from the Swedish eHealth Agency, which included the repayment agreements within inpatient care. Thereby, the cost of inpatient care pharmaceuticals appears to have increased even though it has not necessarily done so. This means that this data does not provide a true and fair view of the pharmaceutical costs in inpatient care.

The following figure shows outpatient and inpatient care sales of pharmaceuticals per capita in Europe. The average amounts to around SEK 4,500. Total sales value per capita is highest in Switzerland (around SEK 7,800 per capita), followed by Austria (SEK 6,300 per capita). Sweden has the twelfth highest sales of all countries with around SEK 4,300 per capita.

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

Figure 3. The sales value in SEK wholesale price per capita sold within inpatient care and outpatient care, respectively, per country



Source: IQVIA and TLV analysis.

Note: Data applies to March 2020, rolling 12 months, rounded to even hundreds. Greece is excluded as there is no available information on inpatient care.

The figure above includes all pharmaceuticals within outpatient and inpatient care. The remainder of this report only covers pharmaceuticals with sales in outpatient care. The reason why the selection is limited to prescription pharmaceuticals in outpatient care is that TLV sets official prices for these pharmaceuticals. Pharmaceuticals in inpatient care have less transparent prices, which complicates such an analysis.

Healthcare providers in different countries may choose to treat the same disease differently. Differences may include different management in terms of what is subject to prescription and what is handled within the scope of inpatient care, and different pharmaceutical therapies, meaning that an ailment is treated with different pharmaceuticals than those used in Sweden. Not all pharmaceuticals are approved or introduced in all countries.

This means that the pharmaceuticals included in the analysis based on a Swedish perspective are not necessarily found in the comparison countries to the same extent. The calculation of a weighted price comparison covering all countries depends on the mix of pharmaceuticals available in the different countries. Prescription medicines in Sweden are not necessarily sold by prescription in other countries. If so, such pharmaceuticals are not included in the calculation.

3 Price comparisons

In this chapter, we present the results of the comparison of Sweden's pharmaceutical prices in relation to other countries. The results are presented in four sections:

- *Prices throughout the pharmaceutical life cycle*
- *Pharmaceuticals without competition*
- *Pharmaceuticals with competition*
- *Bilateral average*

The first section analyses a pharmaceutical's life cycle starting from receiving market approval. The dynamics are analysed over time and for pharmaceutical classes where Sweden has relatively high or low prices in relation to other countries.

In the second and third sections, we analyse Sweden's prices from a Swedish perspective. The division of pharmaceuticals with and without competition is based on the fact that many countries treat the pricing of pharmaceuticals differently depending on whether they are substitutable or not. In Sweden, a pharmaceutical is considered substitutable if it is included in the generic substitution system, the Product-of-the-month. Pharmaceuticals may be non-substitutable due to temporary monopolies caused by patents or that the pharmaceutical is not considered substitutable on medical grounds. Examples of pharmaceuticals generally not considered substitutable despite lacking patent protection include biopharmaceuticals, for example, pharmaceuticals with the substances adalimumab and etanercept,[7] but also synthetic pharmaceuticals not considered therapeutically equivalent. Among inhalation medications for treatment of asthma/COPD, there are generic products that cannot be replaced due to differences in the inhalers used to administer them.

In the final section, we analyse Sweden's prices from the perspective of other countries, using a bilateral average. The analysis is based on the mix of pharmaceuticals used in other countries. This provides a more relevant picture of prices in other countries compared with Swedish prices. Thus, the analysis provides a better idea of how Sweden's pharmaceutical prices compare to other countries' prices, rather than how our pharmaceutical costs would change if we had had the same prices as other countries.

3.1 Prices throughout the pharmaceutical life cycle

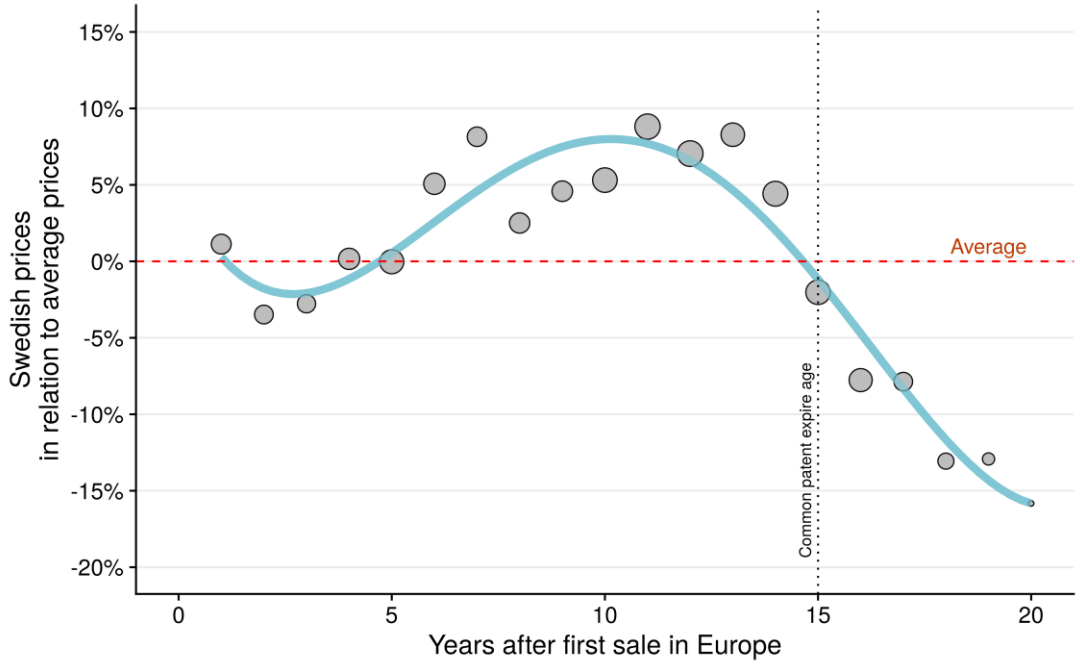
In this section, we present Sweden's price development compared with other European countries' price development based on the first sales in Europe. The analysis covers the entire period from 2014 to 2019 and includes both

[7] Original and reference drugs Humira and Enbrel.

pharmaceuticals with and without competition. To understand the total cost of a pharmaceutical over its life cycle, it is important to look at the price over time, not just at the point of first sale. The fact that the price of older pharmaceuticals drops can have a major impact on the total pharmaceutical costs. New innovations can lead to a drop in the price of existing pharmaceuticals. Thereby, innovation benefits society, both in the form of the innovation itself and in the form of lower prices for the older pharmaceutical.

Figure 4 below shows Sweden's pharmaceutical prices for each year after first sales in Europe compared with the average in the compared countries (up to 20 years after first sales). Sweden's pharmaceutical prices are in line with, or slightly below, the average of the comparison countries during the first five years. Between year 5 and 15, Sweden has more expensive pharmaceuticals. After 15 years, marked with a vertical dotted line, Swedish prices fall to below average.

Figure 4. Sweden's relative pharmaceutical prices in 2014–2020 compared with the average price for the report's 20 European countries. The comparison takes place per year after first sale in Europe.



Source: IQVIA and TLV analysis.
Note 1: The red line shows the average prices for 20 European countries. The position of the circles shows the actual deviation from the average prices, and their size shows how large the sales value is in Sweden for pharmaceuticals of that age. The blue line is an approximate calculation to show the trend over the life cycle. Sales data 2014–2020.
Note 2: The figure shall be interpreted as Sweden's average relative price per pharmaceutical age for all years 2014–2020. Thus, it only tells us what Sweden's relative price level is for the entire period.

The size of the circles shows the 2020 sales value in Sweden. A pharmaceutical's age is calculated based on market approval and not introduction in Sweden. Pharmaceuticals between 5 and 15 years old account for 44 percent of

pharmaceutical costs in 2020 in Sweden[8]. The figure shows that Sweden during the years 2014–2020 has relatively competitive prices upon roll-out and a few years thereafter. After five years, Swedish relative prices start to rise, which is due to prices in other countries falling while the prices in Sweden remain relatively unchanged. Generic competition usually arises after around 15 years from market approval. At that point, the competition within Sweden's Product-of-the-month system forces prices down significantly below the European average.[9]

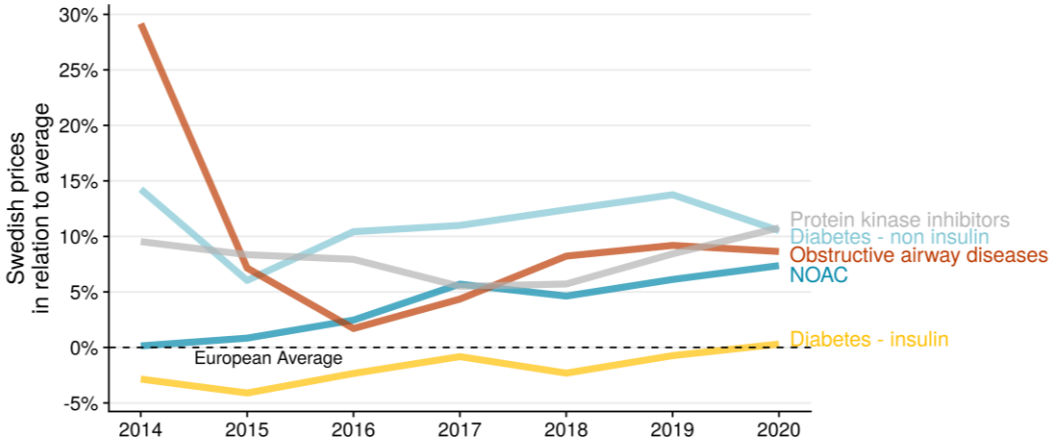
Pharmaceutical prices usually stay at the same level as upon the initial reimbursement decision until it either undergoes a review initiated by TLV or generic competition arises. Pharmaceuticals for which generic competition arises are usually included in the Product-of-the-month system when the Swedish Medical Products Agency has adopted a decision on substitutability at the pharmacy level. For those pharmaceuticals that are not considered substitutable or have weak generic competition, Sweden applies the so-called 15-year rule, which lowers the price by 7.5 percent 15 years after market approval. Thus, the fact that Sweden's relative prices are higher after a few years on the market is not due to prices rising, but that prices are falling in other countries.

The fact that prices in Sweden often remain unchanged over time is illustrated in Figure 5, which shows the price development for the five pharmaceutical classes with the highest sales in 2020 and not covered by managed entry agreements on repayments. The figure uses the 2014 exchange rate to analyse the price development without the effect of exchange rate fluctuations. For all these groups, Swedish relevant prices have increased compared with other countries. The falling prices seen in 2015–2016 are a result of reviews carried out at the time, for example, for asthma/COPD medicines and for certain diabetes medicines.

[8] Pharmaceuticals younger than 5 years account for 20 percent of drug costs and pharmaceuticals older than 15 years account for 36 percent.

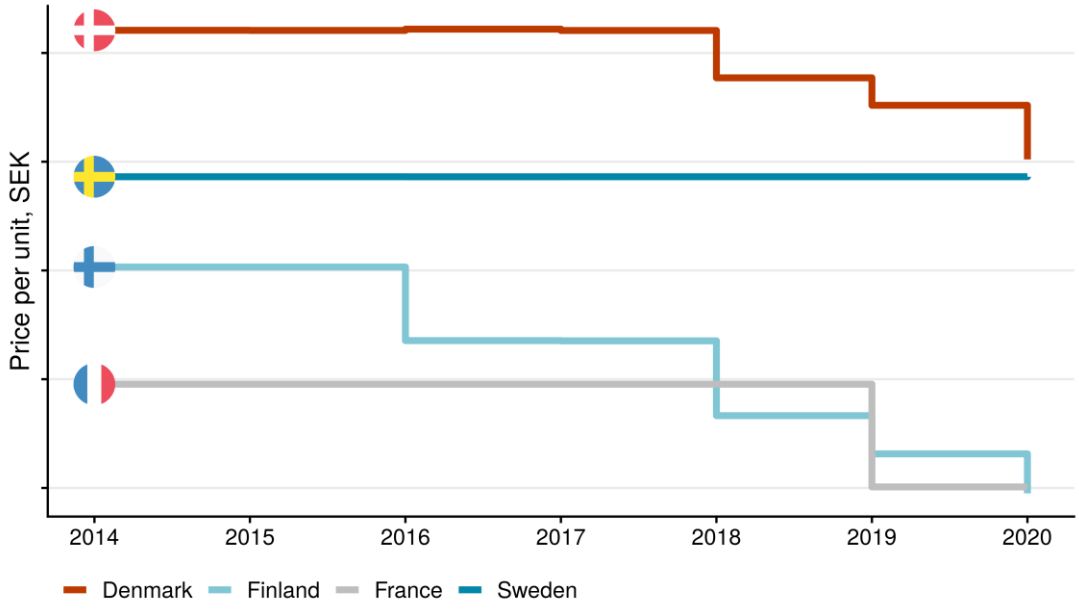
[9] The actual price reduction for the years 15–20 may be more than 15 percent on list price, but as several countries lower the list prices at the same time, the relative reduction will be smaller.

Figure 5. Price development 2014–2020 for the 5 pharmaceutical classes with the highest sales in 2020 without managed entry agreement. Exchange rate Q1 2014 for all years.



The relative price development is illustrated in Figure 6 by Eliquis (apixaban), which belongs to the group NOAC. NOAC is one of the pharmaceutical classes that have seen the highest cost increase in recent years. The price per unit in Sweden has been constant since its introduction, while prices in local currency at the 2014 running exchange rate have been lowered in, for example, Denmark, Finland, and France. Increasing volumes and a steady price have led to major cost increases for Eliquis, which had SEK 1,150 million in sales in 2019, which makes it the pharmaceutical with the highest sales total in outpatient care in Sweden.

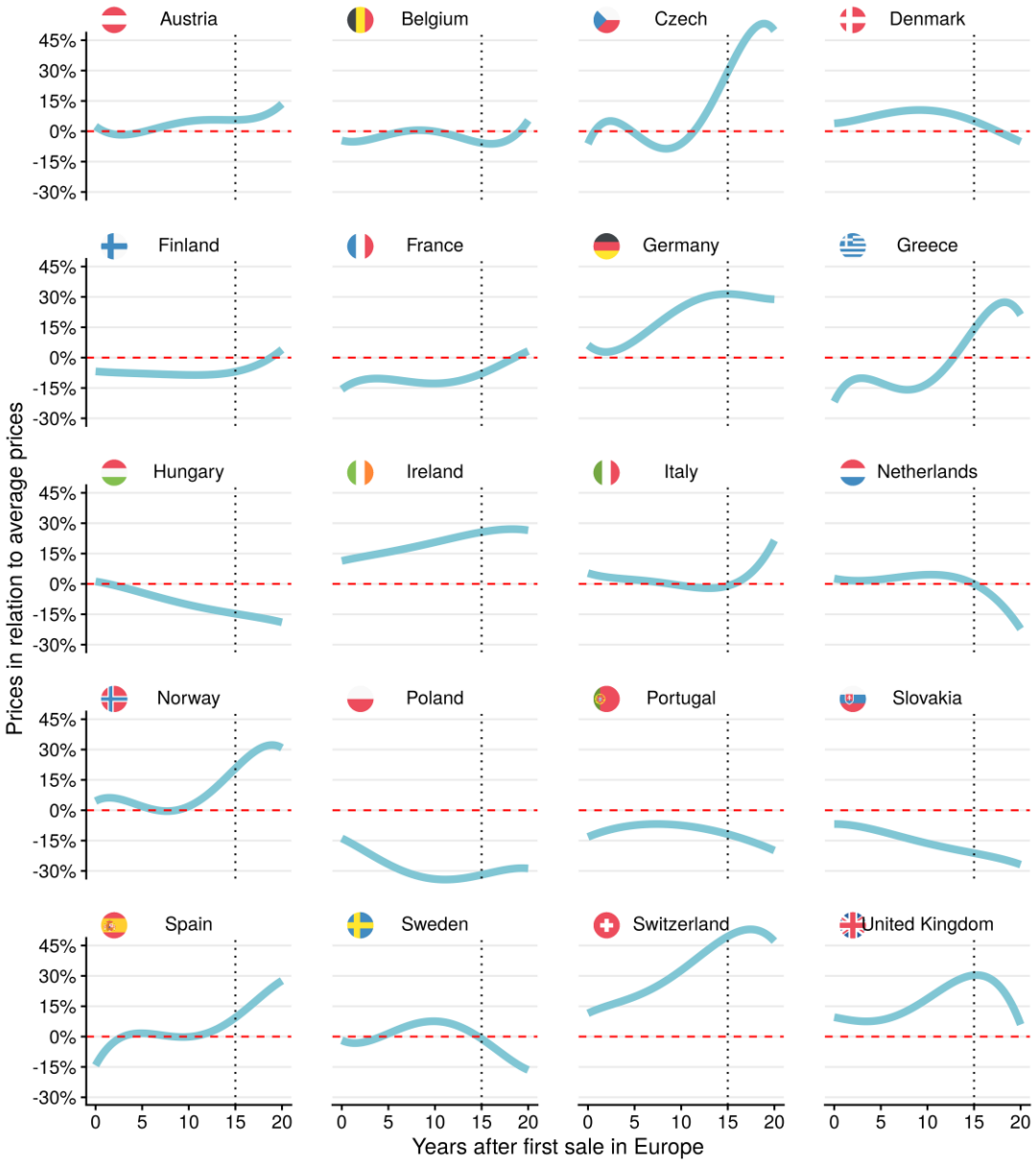
Figure 6. Price development for the substance apixaban 5mg in four countries between 2014–2020. Exchange rate Q1 2014 for all years.



Source: IQVIA and TLV Analysis

Steady prices combined with increasing volumes are the main reason for the cost increases in recent years, which is presented in TLV's report '*Uppföljning av läkemedelskostnader'* [Follow-up of pharmaceutical costs], published earlier in 2020[10]. This means high and steadily increasing costs over time within several areas, such as cancer, diabetes, and NOAC.

Figure 7. Relative list prices of all countries in comparison with the average price for the report's 20 European countries, per year following market approval



Source: IQVIA and TLV Analysis
Note 1: Norway and the Czech Republic 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 transactional prices differ significantly. The observations in this figure only show list prices.
Note 2: The red line shows the average prices for 20 European countries. The blue line is an approximate calculation to show the trend throughout the life cycle. Sales data for outpatient pharmaceuticals, 2014–2020.

[10] Reference Cost Report 2020

Figure 7 above shows the relative price level in relation to the pharmaceutical's age divided among all countries included in the report. Different countries have different institutional conditions and regulatory frameworks for their pricing. These different regulatory frameworks should play a major role in explaining the price dynamics in different countries throughout the life cycle. Sweden has, as previously mentioned, prices in line with the average upon entering the market, but where prices rise compared to other countries for pharmaceuticals between 5 and 15 years old, then fall after patent expiry. Sweden's price patterns throughout the life cycle are similar to those in Denmark and the Netherlands. These countries have systems for generic competition after patent expiry, but do not have automatic mechanisms in place to revise prices between market entry and patent expiry.[11]

Several countries have regulatory frameworks that deal with pharmaceutical prices once the products have been on the market for a few years. One example is Finland, which has time-limited subsidies, valid for a maximum of three years, and where companies must reapply for a subsidy. Finland also has lower prices than Sweden for pharmaceuticals between 5 and 15 years old. Another example is France, which regularly reconsiders price and subsidy status after five years. France also applies volume agreements upon market entry, which are then converted into list price reductions after a number of years according to framework agreements with manufacturers. Another mechanism for controlling prices is a strict pharmaceutical budget with repayments from manufacturers if exceeded. For a more detailed description of different countries' regulatory frameworks, see Appendix 2.

Countries that have a generic substitution system, which rewards the pharmaceuticals with the lowest prices, see falling pharmaceutical prices after 15 years on the market. This is evident from Figure 7 for Sweden, Denmark, and the Netherlands. Norway's results for pharmaceuticals older than 15 years must be interpreted with caution as Norway's list prices on which this report is based are not necessarily the same price at which pharmacies buy or sell the pharmaceutical.[12] For more information on the Nordic countries, please see the 2018 report and the section *Nordic outlook*.

3.2 Pharmaceuticals without competition

Price development in Sweden depends on the competition between pharmaceuticals. Pharmaceuticals without competition mainly include pharmaceuticals under patent protection and where there are no generics with the same active substance. Pharmaceuticals not deemed substitutable by the Swedish Medical Products Agency for pharmacy dispensation are also included in this group despite the fact that patents have expired.

In Sweden, value-based pricing is used, which means that TLV makes health economic evaluations of pharmaceuticals before they are subsidised within the framework of the annual maximum health bill (high-cost protection). The health

[11] For requisition pharmaceuticals, Denmark also has an agreement with the manufacturers where the prices of older pharmaceuticals are reduced by 12.5 percent over a four-year period.
[12] Norway applies a stepped pricing model for generic pharmaceuticals. This model links the price to the time after various numbers of competitors have entered the market and to sales volume. Thus, the Norwegian drug prices found in the dataset are not necessarily representative.

economic evaluation includes an assessment of whether the costs of a pharmaceutical are reasonable in relation to the benefit that the treatment provides. In most countries, including Sweden, different types of repayment agreements are used for reimbursement of pharmaceutical costs from companies to payers, in Sweden's case the regions, which reduce the actual costs of pharmaceuticals compared with official prices (PRP in Sweden). See *Appendix 2* for a more detailed description of different countries. Before generic competition arises, or when competition between pharmaceuticals is stimulated through reviews or tripartite deliberations, prices in Sweden are usually constant. There is rarely spontaneous price competition between pharmaceuticals in this category, which contributes to these pharmaceuticals constituting a large and growing share of pharmaceutical costs in Sweden as volumes increase.

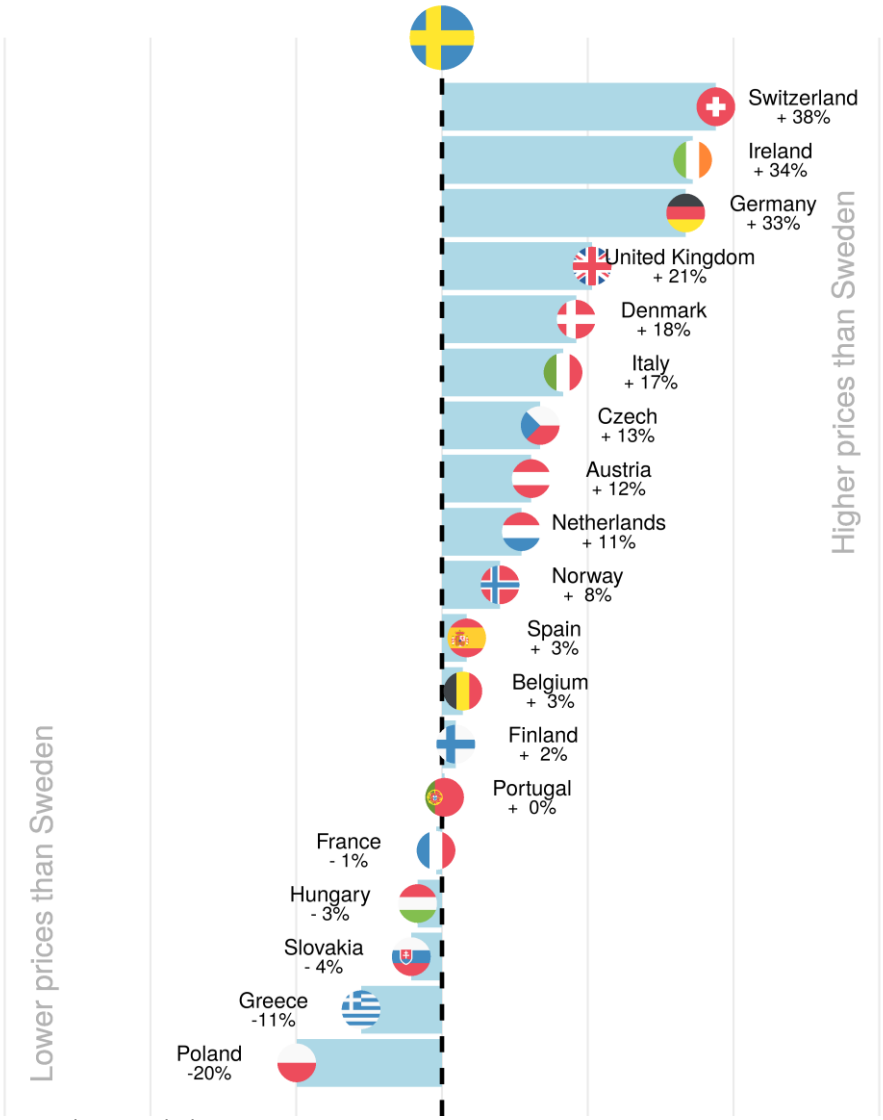
3.2.1 Bilateral price comparison 2020 for pharmaceuticals without competition

When analysing pharmaceutical prices without competition, it becomes clear that there are significant differences between the countries included in the comparison. Figure 8 shows a bilateral price comparison where Sweden's prices during Q1 2020 are compared with other countries' prices during the same period. The comparison is made in pairs, which means that the pharmaceuticals with sales both in Sweden and in each individual country are included in the comparison. Thus, different pharmaceuticals are compared with different countries, and it is only possible to make comparisons with Sweden.[13]

The bilateral comparison is also weighted based on the volumes prescribed in Sweden and shows what *the Swedish pharmaceutical use, with Swedish volumes, would have cost if other countries' prices were applied*.

[13] For example, it is not possible to say that Germany has higher prices than Ireland, as it is not certain that the same pharmaceuticals are being compared.

Figure 8. Bilateral price comparison for pharmaceuticals without competition, 2020



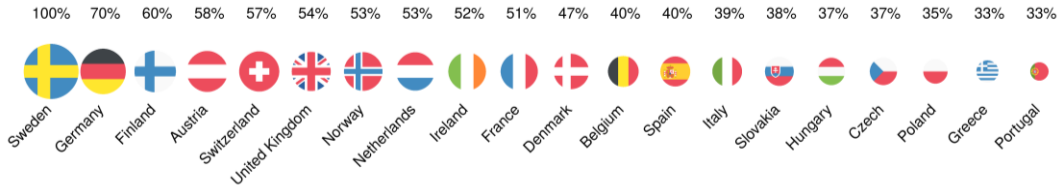
Source: IQVIA and TLV analysis.
Note: Prices during Q1 2020. Volumes running 12 months up to and including March 2020. 3-year average exchange rate.

The price difference in the figure above shall be interpreted as Switzerland having 38 percent higher pharmaceutical prices than Sweden for the pharmaceuticals without competition available in both countries. Sweden has lower prices than 13 of the countries, higher prices than five of the countries, and no price difference compared with one country (Portugal). The countries with lower prices than Sweden generally have a low matching rate with respect to Swedish use, meaning that the results must be interpreted with caution. Countries with higher prices than Sweden generally have a higher matching rate. The concept of a matching rate and its significance for the analysis is described in the next section.

3.2.2 Matching rate

The matching rate illustrates the proportion of prescription pharmaceuticals sold at pharmacies in Sweden that are also available in other countries and sold at pharmacies. Pharmaceuticals used within inpatient care 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 details.

Figure 9. Swedish matching rate for pharmaceuticals without competition



Source: IQVIA and TLV analysis.

In Sweden, there are a total of 11,040 pharmaceuticals in the selection for this segment. These pharmaceuticals form the basis of the price comparison with other countries. Sales of pharmaceuticals in other countries that do not match those available in Sweden have therefore been excluded (even if the substance itself is available in other countries). The number of pharmaceuticals that exist in Sweden (counted as substance, form, and strength) is therefore the maximum number of pharmaceuticals.

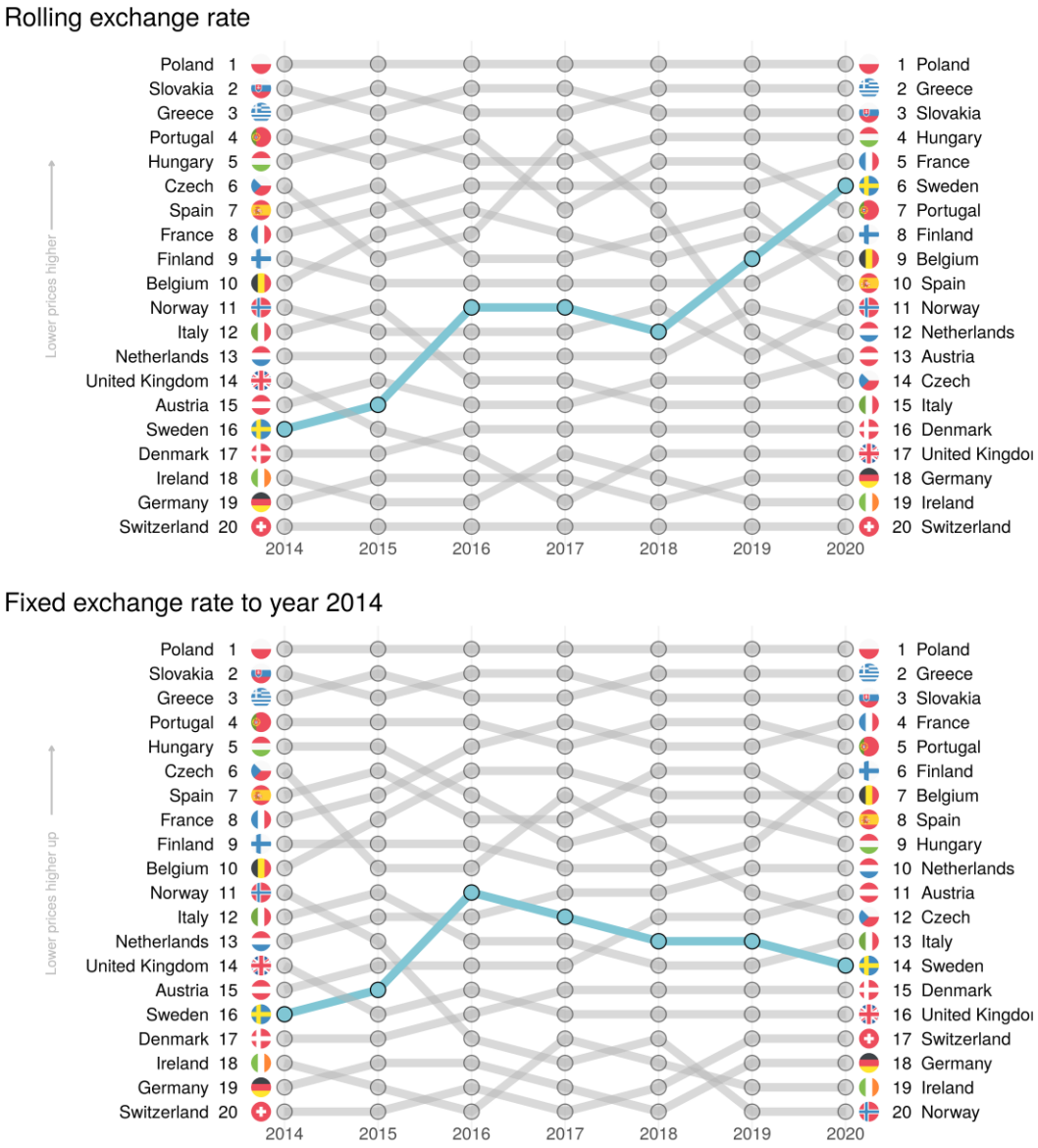
On average, the matching rate is highest for Germany, where 70 percent of the pharmaceuticals used in Sweden are used. Germany is followed by Finland, Austria, Switzerland, the United Kingdom, Norway, and the Netherlands with a matching rate between 53 and 60 percent. The lowest matching rate is with countries such as Portugal, Greece, Poland, the Czech Republic, Hungary, Slovakia, and Italy, all of which have a matching rate below 40 percent. A comparison between Germany and Sweden is thus based on 70 percent of the pharmaceuticals available in Sweden and a comparison with Portugal is based on only 33 percent. In bilateral price comparisons, it is thus only possible to compare each country with Sweden, not other countries with each other.

Differences in the matching rate between countries are important to consider when studying 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 with very low matching rates are more difficult to generalise, as the comparison is only relevant to the few products that the countries have in common. The fact that different pharmaceuticals are included in the comparison with each country also means that it is impossible to make a paired comparison between other countries than Sweden. One alternative to the bilateral comparison is to calculate a bilateral average for all countries. This analysis is presented in section 3.4.

3.2.3 Historical development

Sweden's prices for pharmaceuticals without competition have decreased in relation to other countries. In 2020, Sweden ranks in sixth place, where first place is for the country with the lowest price. This means that five countries have lower prices, and 15 countries have higher prices than Sweden. In 2014, Sweden ended up in sixteenth place, as only four countries had higher prices. This means that prices have decreased in Sweden compared with other countries. The declining relative prices are primarily an effect of the Swedish krona losing value against other currencies in recent years. Note, however, that Swedish volumes are used in the analysis, which gives Sweden an advantage as pharmaceuticals tend to be less expensive if they are used frequently. Figure 10 shows the development between 2014 and 2020 for all countries included in the comparison. The bottom figure shows Sweden's relative prices when the exchange rate is kept constant.

Figure 10. Development of the bilateral price comparison over time, 2014 - 2020. 3-year average exchange rate.



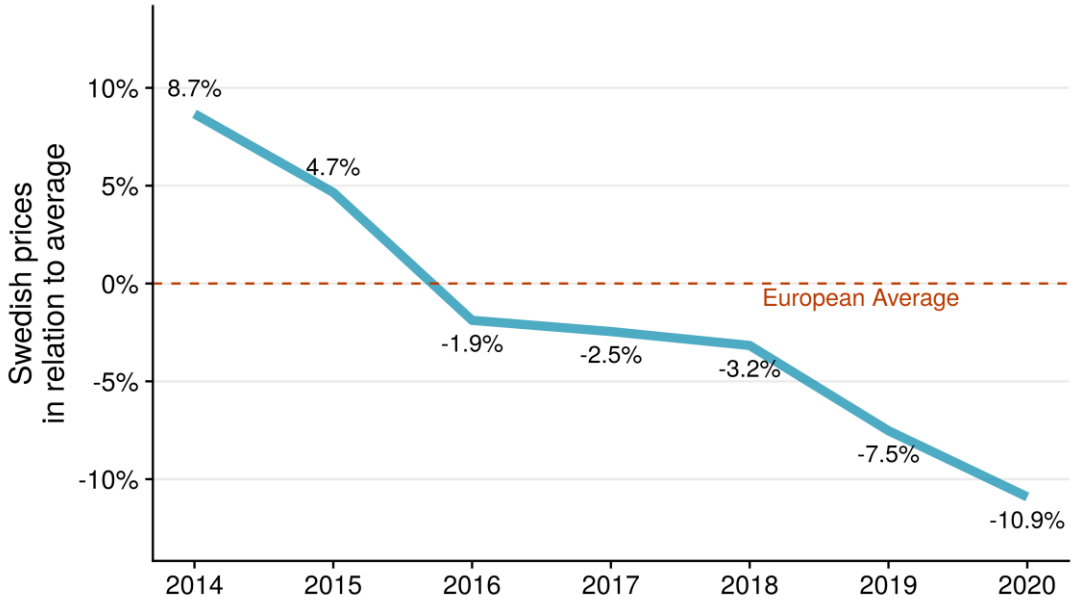
Source: IQVIA and TLV analysis.
Note 1: Rank 1 means that the country has the lowest prices. Rolling 3-year average exchange rates per year.
Note 2: When using bilateral comparison with Sweden's volume weights, no interpretations shall be made between countries other than Sweden.

The top figure shows how Sweden's prices have changed in relation to other countries between 2014–2020. During the period, Sweden has gone from having the sixteenth to the sixth lowest prices. The main explanation for this change has been the exchange rate. In the bottom figure, where the exchange rate is kept constant, Sweden has moved from sixteenth to fourteenth place. Sweden's prices fell in relation to other countries between 2015 and 2016, when many reviews of reimbursement status were done and the 15-year rule, with a price reduction for older pharmaceuticals by 7.5 percent, was introduced in 2015. From 2016 onwards, Sweden's relative prices have instead risen slightly when the exchange rate effect is deducted.

The percentage difference in price level between the countries is in many cases small. Sweden's placement 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 placement compared with other countries.

Figure 10 shows that Sweden's prices in relation to the rest of Europe have decreased since 2014. To get a better picture of the development, it is also interesting to look at the size of this change. Figure 11 shows the percentage deviation between prices in Sweden and the average prices in other countries from 2014 to 2020.

Figure 11.Sweden's relative prices compared with the average per year, calculated as a cross-section. Pharmaceuticals without competition



Source: IQVIA and TLV analysis.

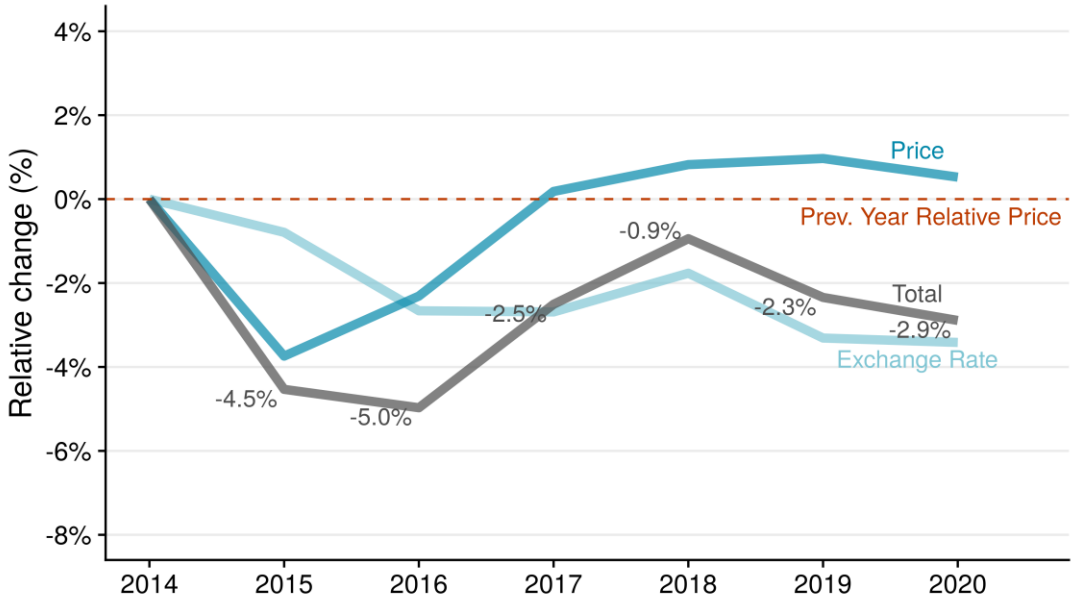
Note: Calculation based on cross section. Exchange rate 3-year running average each year.

The figure shows that Sweden's prices in 2014 were 8.7 percent higher than the average for all countries. Over time, Sweden's prices have gradually decreased by just over twenty percentage points until the first quarter of 2020, when Sweden's prices were 10.9 percent lower than average. The change is mainly driven by the exchange rate change.[14] From 2014 to 2016, however, the relative price reduction was mainly driven by reviews of reimbursement status and the introduction of regular price reductions for pharmaceuticals 15 years and older. As previously mentioned, Swedish prices are likely to rise if the Swedish krona increases in value again. The following section provides a more detailed description of the reasons behind this price development.

3.2.4 Drivers of relative price

Sweden's relative pharmaceutical prices compared with other European countries are influenced by several different factors. As previously mentioned, it is clear that the weakened Swedish exchange rate contributes to the relatively low Swedish price level. Figure 12 shows the proportion of the change in the relative price level between each year driven by changes in the exchange rate and the proportion driven by actual price changes on pharmaceuticals in both Sweden and other countries.

Figure 12. The transformative effects of the relative price divided into price and currency changes. Pharmaceuticals without competition weighted according to the use in Sweden in 2014.



Source: IQVIA and TLV analysis.

The *currency* category includes the part of Sweden's relative price level entirely driven by the falling Swedish krona. The second category, *price,* is influenced in part by changes in pharmaceutical prices in the rest of Europe, and partly by changes in Swedish pharmaceutical prices. The negative price change effect in the

[14] A version of the figure, with a fixed exchange rate, can be found in section 1.1 of Appendix 1.

figure above can thus be due to falling prices in Sweden *or* rising prices in other countries. The 2015 price reduction effect is mainly due to price reductions as a result of reviews of reimbursement status in Sweden. Since 2016, reviews have also been made as regions and companies have signed managed entry agreements on repayments, which has contributed to lower costs. This has happened, for example, among TNF inhibitors and factor VIII/IX preparations. The size of the reduced costs as a result of managed entry agreements is not public and is therefore not included in this report.

In order to separate the price effect from the changes in costs due to the varying degree of use of different pharmaceuticals over the years, only the pharmaceuticals used between 2014 and 2020 are included in the analysis. For the same reason, the use is weighted based on how these pharmaceuticals were used in 2014. As in previous analyses based on cross-sections, the price category is weighted based on how much use a certain pharmaceutical has in Sweden. Meaning, price changes on pharmaceuticals with high use have a greater effect than an equally large price change on a pharmaceutical with lower use.

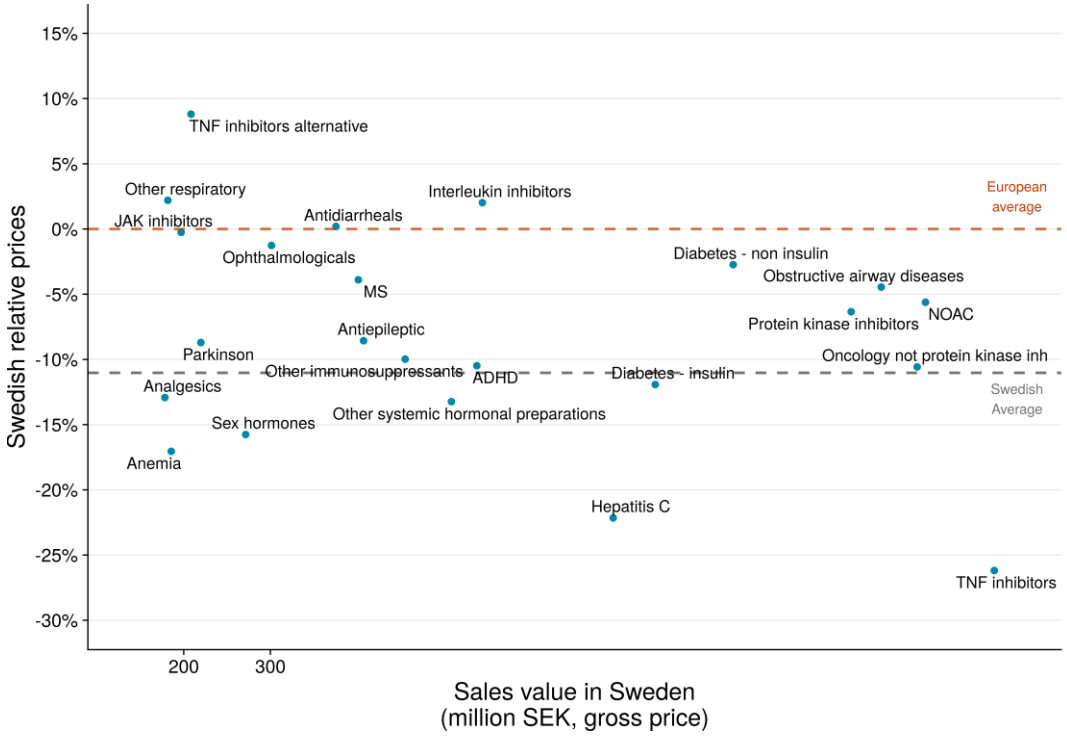
The sum total of the price and currency components form the category *Total relative price change*. A negative total effect below the dashed red line means that Swedish relative prices are *lower* compared with the previous year.[15] A more detailed description of the calculations and methodology behind the figure is presented in section 2 of Appendix 1.

Figure 12 shows that the explanation behind Sweden's falling relative price level is mainly found in the falling value of the Swedish krona. During 2015–2016, actual price changes also contributed to Sweden's relative price level dropping further. The price changes were mainly a result of reviews of reimbursement status made for TNF inhibitors and pharmaceuticals for obstructive airways diseases (asthma/COPD medicines). Prices were also reduced during this period as a result of the 15-year rule introduced in 2014. In all the years since 2017, the relative Swedish price level would have been raised if not for the falling Swedish krona. This can be explained by the fact that fewer reviews of reimbursement status were done and those that were led to smaller price reductions. In several cases, costs were reduced through managed entry agreements between pharmaceutical companies and regions instead of reducing PRP. However, the analysis clarifies that, from an international perspective, Swedish pharmaceutical prices are sensitive to exchange rate fluctuations.

To examine price differences on a more detailed level, Figure 13 shows Sweden's prices in comparison with Europe as well as sales in Sweden in 2020,[16] split into different pharmaceutical classes.[17]

[15] The total line in Figure 13 corresponds to the rate of change (derivative) of a line similar to that shown in Figure 12, but for a selection of pharmaceuticals according to the use in 2014.
[16] The sales amount is calculated as the price range during Q1 2020 multiplied by the volume rolling 12 months for each pharmaceutical Q1 2020.
[17] For more information on drug classes, see *Appendix 1* and the subheading *Drug classes*.

Figure 13. Swedish prices for pharmaceutical classes in comparison with the European average wholesale price, 2020. Pharmaceuticals without competition



Source: IQVIA and TLV analysis.

Note: Note that the x-axis intervals are increasing exponentially. This is so that all pharmaceutical classes can be shown together. Pharmaceutical classes with API sales of less than SEK 150 million have been excluded for the same reason.

The figure shows that, for example, the pharmaceutical classes TNF inhibitors and oncology excluding protein kinase inhibitors have high sales in Sweden but comparatively low list prices in relation to other countries. The pharmaceutical classes IL inhibitors, antiepileptics, obstructive airways diseases, diabetes excluding insulin, NOAC, and protein kinase inhibitors all have high sales in Sweden. In previous years, Swedish prices for these groups were above, or on par with, the European average. As the Swedish krona weakened further during 2019–2020, the price level is currently below the European average. If the Swedish krona were to strengthen, the prices of these pharmaceuticals would be higher in relation to other countries and the European average. Although the price level for these pharmaceutical classes is lower than the European average, they are above the average relative price level for pharmaceuticals in Sweden. For these groups in particular, there are no managed entry agreements but only official list prices.

Within several groups shown in Figure 13, there are pharmaceuticals with managed entry agreements. This means that, in reality, the cost of using these is lower than what is stated by its price level. This includes pharmaceuticals within the classes Protein kinase inhibitors, TNF inhibitors, and Hepatitis C.

Overall, Swedish pharmaceutical prices without competition have become lower relative to average European prices. This trend is mainly due to the Swedish krona

having decreased in value against the Euro. Measured in SEK, prices are usually stable until generic competition arises in the Product-of-the-month system or when competition is stimulated by TLV making reviews of price and reimbursement status or when regions and companies sign managed entry agreements on repayments. Without interventions or rule-based price reductions, we rarely see spontaneous price competition between pharmaceuticals on the Swedish market.

3.3 Pharmaceuticals with competition

Pharmaceuticals with competition are this report defined as pharmaceuticals covered by the generic substitution at pharmacies in Sweden, the Product-of-the-month system. In Sweden, pharmaceuticals with the same substance, dosage form, strength, and package size group may apply for a price and report availability for the Product-of-the-month system. Of the packages where availability can be guaranteed, the product with the lowest price is designated as the product of the month, which means that pharmacies must switch to this product instead of the package prescribed. Patients may decline to change to a generic product, but must then pay the additional cost out of pocket. This system provides large sales volumes for the pharmaceuticals that have the status of product-of-the-month and thus leads to price competition between pharmaceutical companies.

Generic substitution systems linked to the lowest price over a period of time are available in several versions in different countries. *Appendix 2* includes a description of all countries. Some examples from other countries are:

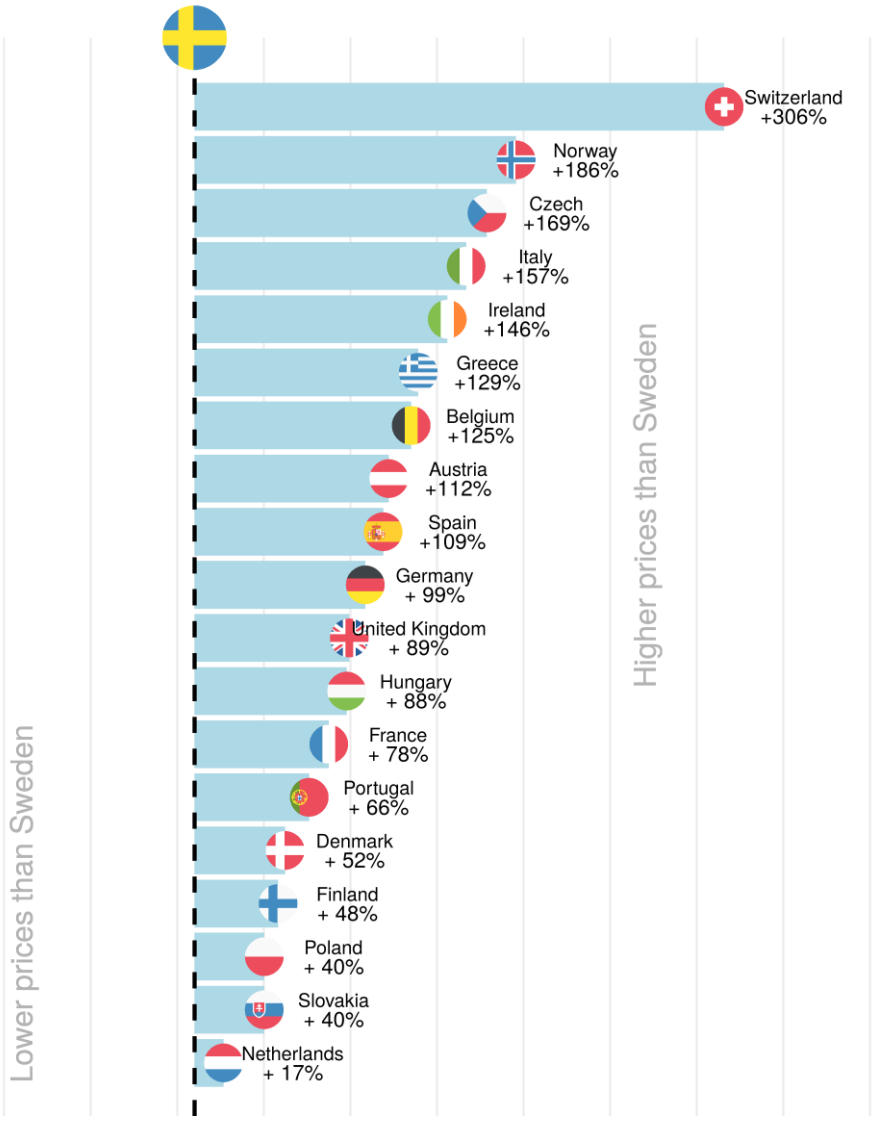
- Denmark uses sales periods of two weeks compared to one month in Sweden.
- The Netherlands has a period of 3, 6, 12, or 24 months.

The systems for generic substitutions in these countries differ, but the basic idea is the same. The pharmaceutical with the lowest price within a defined substitution group is the pharmaceutical that primarily shall be sold at pharmacies for a given period. Norway applies a stepped price model for generic pharmaceuticals. The model involves linking the price to the time after different numbers of competitors have entered the market and to sales volume. Other examples include Austria, France, and Ireland, which link price reductions on original and generic pharmaceuticals to certain periods of time after competing pharmaceuticals entered the market.

3.3.1 Bilateral price comparison 2020 for pharmaceuticals with competition

This report shows significant differences between countries in prices among pharmaceuticals with competition. Relative prices vary more than among pharmaceuticals without competition, as presented in the previous section.

Figure 14. Bilateral price comparison for pharmaceuticals with competition, 2020



Source: IQVIA and TLV analysis.

Note: Prices Q1 2020. Volumes running 12 months up to and including March 2020. 3-year average exchange rate.

Figure 14 shows a bilateral price comparison for pharmaceuticals with competition, where Sweden's prices during the first quarter of 2020 are compared with other countries' prices during the same period. The comparison is paired, which means that pharmaceuticals with sales both in Sweden and in the country in question are included in the comparison. It is clear from the figure that the Swedish prices of pharmaceuticals used both in Sweden and Spain would have increased by 109 percent if the Spanish prices had been applied.

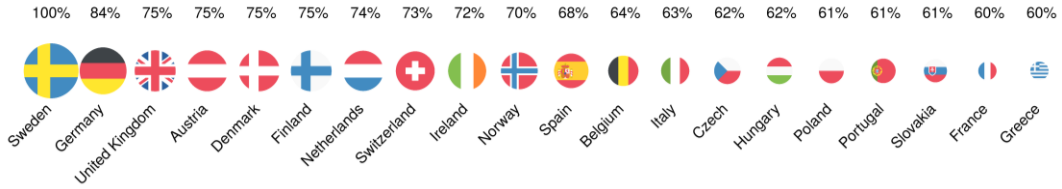
In the bilateral price comparison for Sweden and the other 19 countries, Sweden has the lowest prices. The Netherlands has the closest price level to Sweden's. The Netherlands has generic substitution at the pharmacy level, which creates competition between generic packages of the same pharmaceuticals. Switzerland has significantly higher prices than Sweden. If Sweden had the same prices as

Switzerland and used the same volumes as today, Sweden's prices of pharmaceuticals with competition would be three times higher.

3.3.2 Matching rate

The matching rate illustrates the proportion of the pharmaceuticals available in Sweden and included in the selection that are also available in other countries. The starting point is only the pharmaceuticals available in Sweden that also exist in other countries. Pharmaceuticals with significantly less sales per capita than Sweden are excluded from the comparison.[18]

Figure 15. Swedish matching rate for pharmaceuticals with competition



Source: IQVIA and TLV analysis.

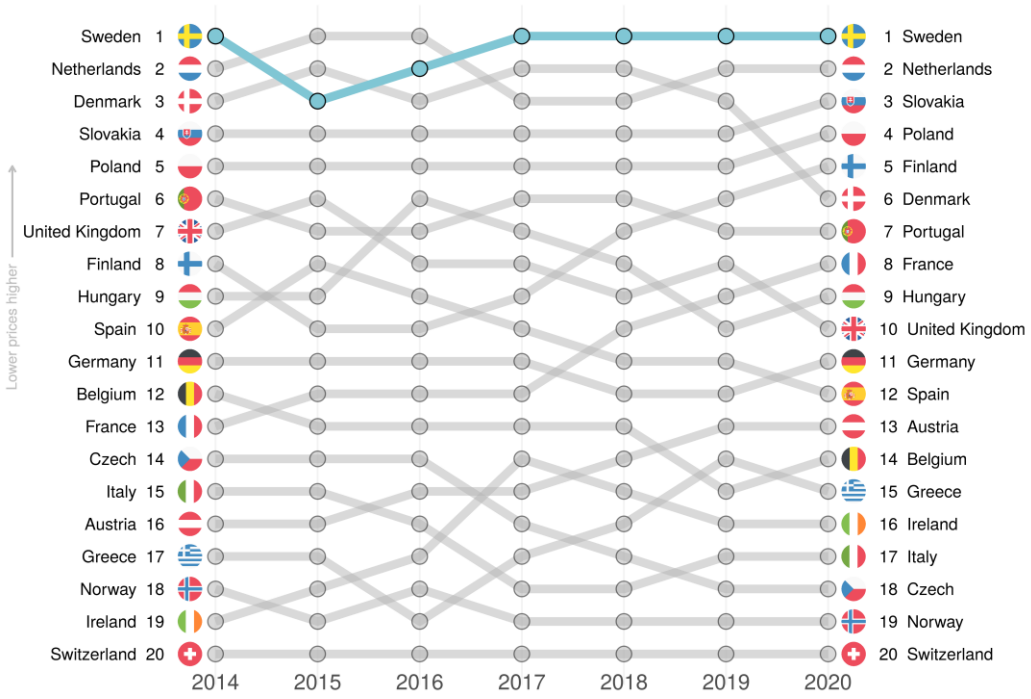
In Sweden, there are a total of 623 pharmaceuticals in the selection of pharmaceuticals with competition. These pharmaceuticals form the basis for the bilateral price comparison with other countries. In the segment Pharmaceuticals with competition, the matching rate is generally significantly higher than for Pharmaceuticals without competition.

3.3.3 Historical development

Sweden's prices within pharmaceuticals with competition have been among the lowest during the years 2014 to 2020 compared to the other countries in the comparison. In 2020, Sweden had the lowest prices in the segment. Figure 16 shows the ranking development for each country in the comparison. First rank means that the country has the lowest prices. Denmark and the Netherlands are the two countries that were closest to Sweden during the years 2014 to 2019, but between 2019 and 2020, Denmark ranked in sixth place. Three countries that have seen significant relative price reductions between 2014 and 2020 are Finland, Greece, and France.

[18] If the use is less than 0.5 percent of the use in the base country, the drug is excluded from the comparison.

Figure 16. Development of the bilateral price comparison over time, 2014 - 2020. Pharmaceuticals with competition

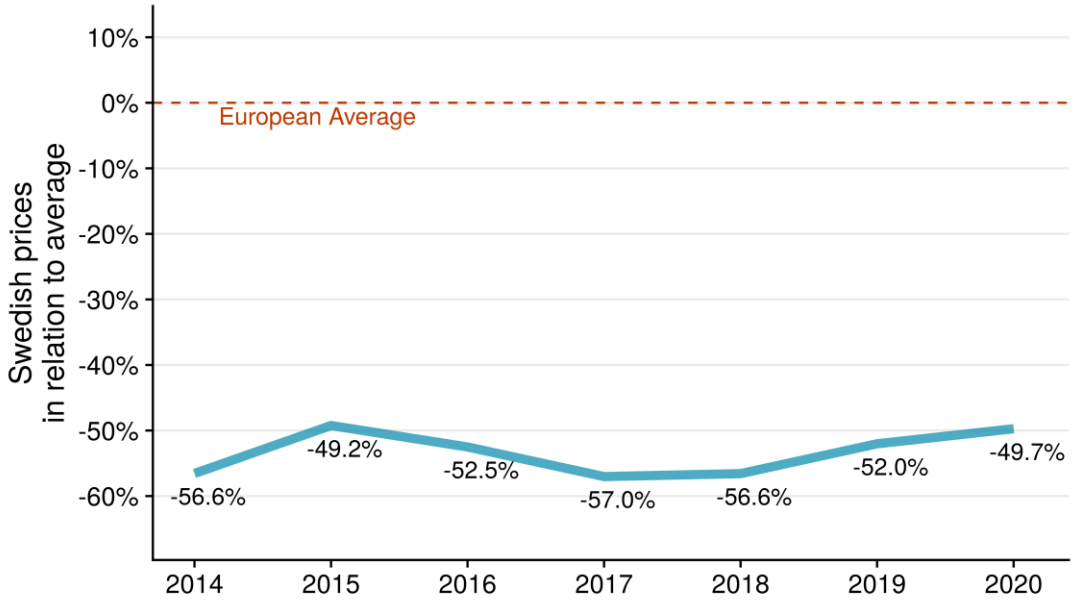


Source: IQVIA and TLV analysis.
Note 1: Rank 1 means that the country has the lowest prices. Running 3-year average exchange rates per year.
Note 2: As the bilateral comparison uses Sweden's volume weights, interpretations between countries other than Sweden shall not be made.
Note: Some countries have general discount systems not shown in list prices and may give a potentially different picture than the one shown here.

The ranking over time, as seen in Figure 16, shows that Sweden continues to have among the lowest prices in comparison with other countries since 2014. However, the figure above does not show how much pharmaceutical prices have changed compared with other countries. Figure 17 below shows how Sweden's prices of pharmaceuticals with competition compare percentagewise with the average of all countries in the report.

As the figure above shows, Denmark has gone from the third lowest price to the sixth lowest price between 2019 and 2020. This is due to some pharmaceuticals rapidly increasing in price during the first quarter of 2020. Such a development is more unlikely in Sweden, where the Product-of-the-month system has ceiling prices.

Figure 17.Sweden's relative prices compared with the average per year, calculated as a cross-section. Pharmaceuticals with competition



Source: IQVIA and TLV analysis.

Note: Calculation as cross section. Exchange rate 3-year running average each year.

The figure above shall be interpreted to mean that Sweden's prices of pharmaceuticals with competition in 2014 were almost 57 percent lower than the average for the 20 countries included in this report. In 2020, Sweden's pharmaceutical prices have increased to just under 50 percent below average. This is the other side of the coin with a weaker Swedish krona. The Product-of-the-month system allows price increases, up to a potential ceiling price, as a result of the pharmaceutical costs being higher in other countries. The competitive situation in the segment influences the price level and it is in turn influenced by the international price situation.

3.3.4 Drivers of relative price

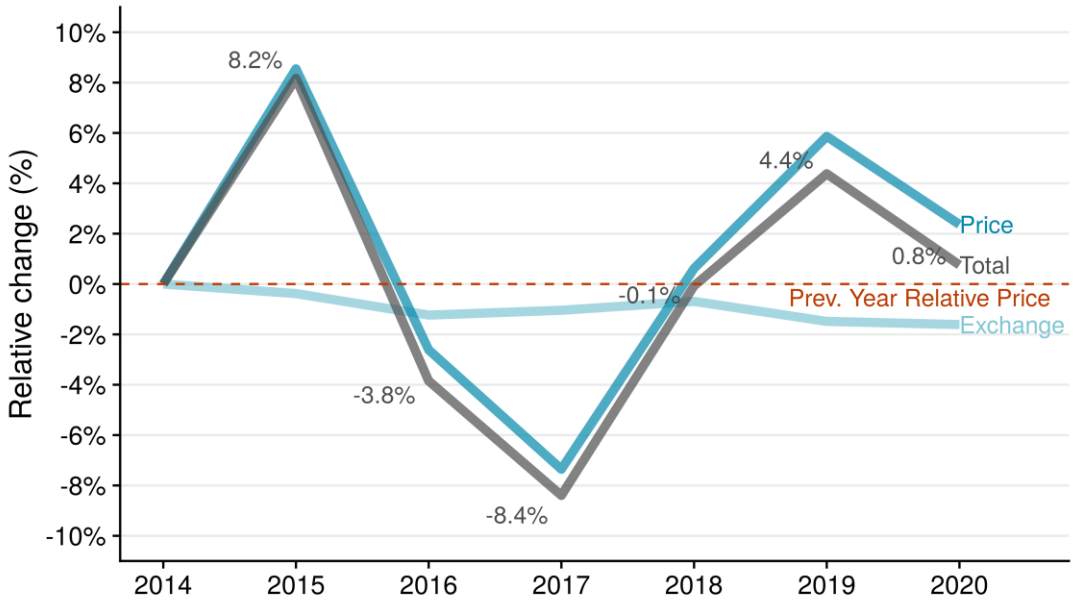
Figure 18 shows the proportion of the total change in Sweden's relative price level, during the period 2014–2020, which has been driven by the falling value of the Swedish krona and the proportion explained by actual price changes. The price change captures the part of the relative price affected by actual price changes; the currency change captures the relative price change due to the falling Swedish currency. A more detailed description of these effects is provided in section 3.2.4 and in section 2 of Appendix 1.

For the period 2019–2020, Swedish prices of pharmaceuticals with competition have increased compared with Europe in general. The figure shows that the price increase is mainly driven by a change in actual prices. However, the falling exchange rate slightly reduces the negative effect of price change. During the period 2016–2018, however, both exchange rate changes and changes in actual prices

contributed to the Swedish relative price of pharmaceuticals with competition falling.

It should be pointed out that in practice, for pharmaceuticals within the Product-of-the-month system, prices can change on a monthly basis. This means that pharmaceutical companies can compensate for changes in the value of the Swedish krona with a corresponding change in price, which means that the currency effect is directly adjusted through a price change. This is probably the main reason why the effect of currency changes is relatively smaller compared with pharmaceuticals without competition (compare Figure 12).

Figure 18. The change effects of the relative price divided into price and currency changes. Pharmaceuticals without competition weighted based on the use in Sweden in 2014.



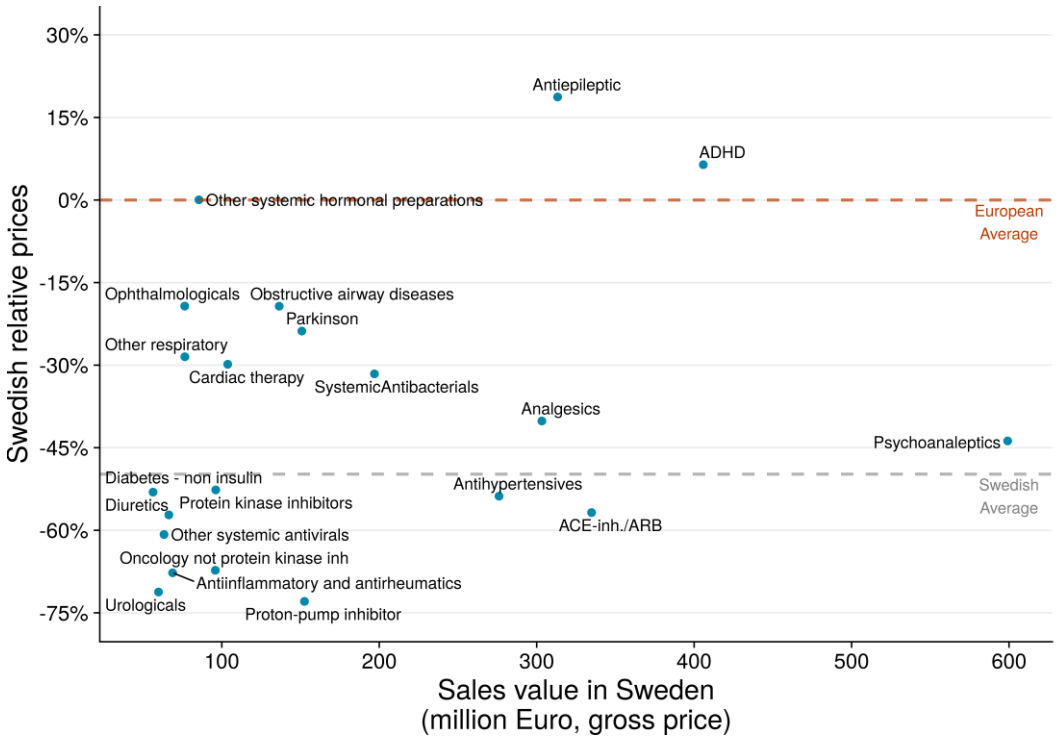
Source: IQVIA and TLV analysis.

3.3.5 Pharmaceutical classes

As previously demonstrated, Swedish pharmaceutical prices exposed to generic competition are generally lower than in other European countries. Figure 19 shows Sweden's prices in comparison with Europe, as well as sales in Sweden in 2019[19] divided into different pharmaceutical classes.

[19] The sales amount is calculated as the price range for Q1 2020 multiplied by the volume for each pharmaceutical between Q2 2019 and Q1 2020.

Figure 19. Swedish prices for pharmaceutical classes in comparison with the European average wholesale price, 2020. Pharmaceuticals with competition



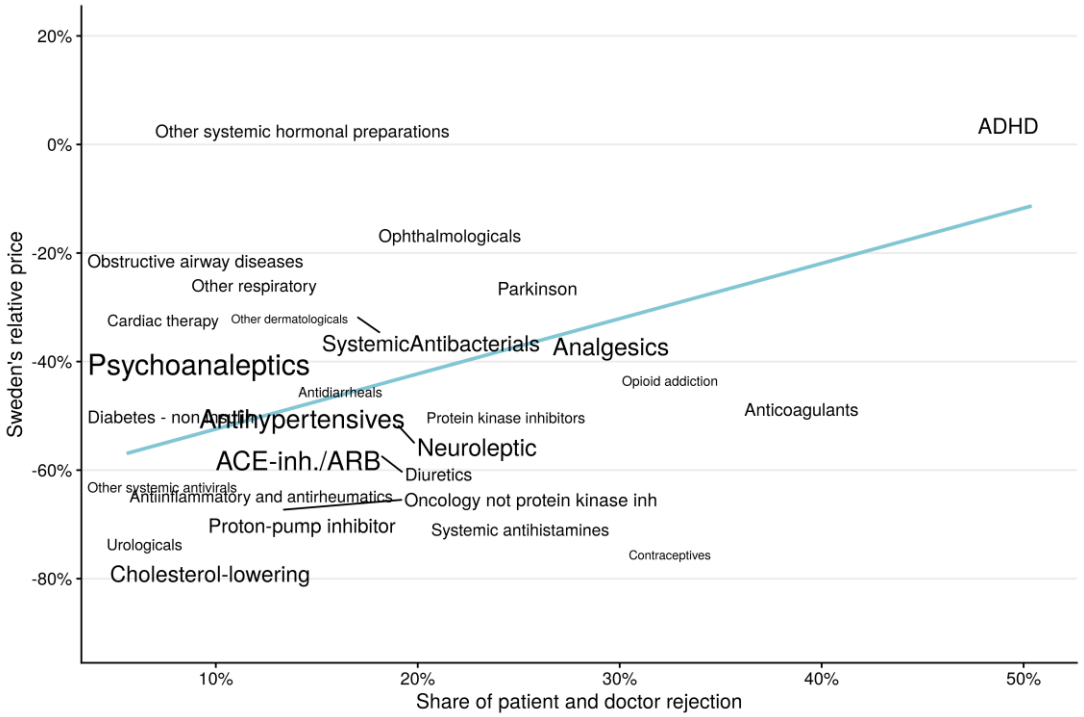
Source: IQVIA and TLV analysis.

Note: Note that pharmaceutical classes with sales at (wholesale price) of less than SEK 50 million were excluded to be able to show classes.

The figure shows that prices are below or in line with the European average for all but two classes, antiepileptics and ADHD medicines, both of which are above the European average. For the antiepileptics, the substitution at pharmacy level is limited by the fact that pharmaceuticals for treatment of epilepsy are not considered by the Swedish Medicines Agency to be substitutable with other pharmaceuticals with the same substance, even though these are bioequivalent.[20] Only certain strengths of some substances that also have another indication than epilepsy are substitutable. The substitution of ADHD medicines is also limited for, for example, methylphenidate, where the prescriber in around 40 percent of all filled prescriptions has marked that the prescribed pharmaceutical should not be substituted by the pharmacy. In addition, patients reject substitution in around 15 percent of all filled prescriptions for methylphenidate. There is a relationship between Sweden's relative prices for specific pharmaceutical classes and the proportion of all prescriptions where either the prescriber or patient has opposed substitution (see Figure 20).

[20] Swedish Medical Products Agency 2019, Pharmaceuticals for epilepsy - treatment recommendation. Information from the Medical Products Agency 2019; 30 (3) 19–38.

Figure 20. Swedish prices for pharmaceutical classes compared with the European average wholesale price and proportion of patient and prescriber rejections, Q1 2020. Pharmaceuticals with competition



Source: IQVIA, the Swedish eHealth Agency, and TLV analysis.

Note: The pharmaceutical class text size shows the sales amount in wholesale prices.

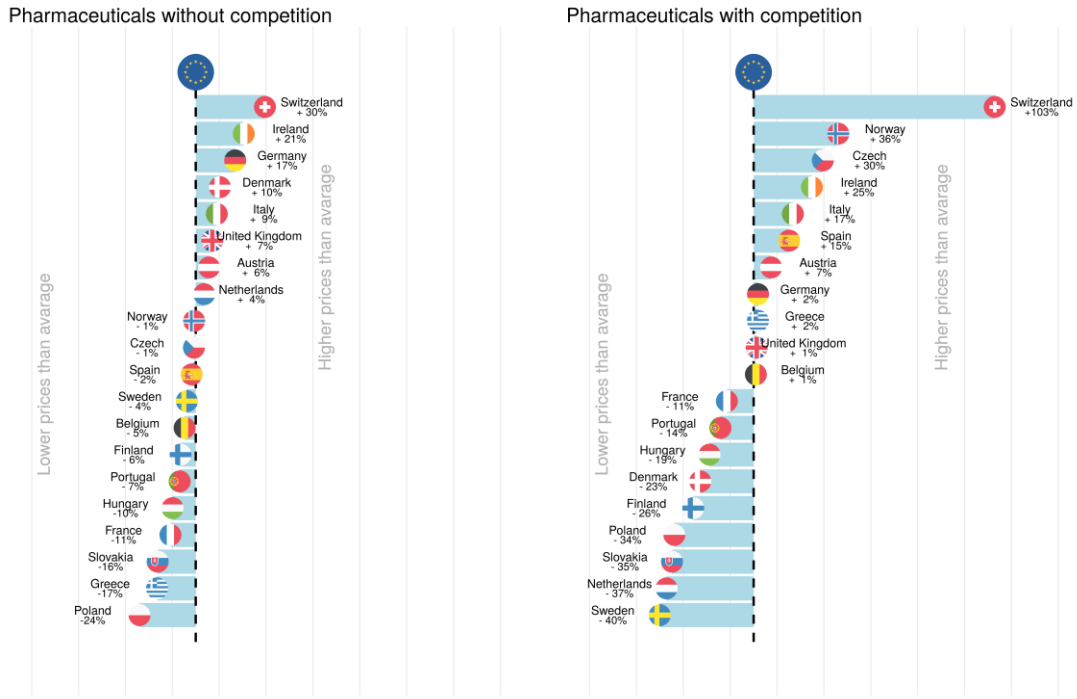
Figure 20 also shows that, within several pharmaceutical classes, a sizeable proportion of all prescriptions are not substituted because either the patient or the prescriber rejects it. The relationship between the proportion of marks and the relative prices indicates that limitations on substitution impact the effectiveness of price competition within individual pharmaceutical classes.

3.4 Bilateral average – price comparison considering other countries' volumes

Above, Swedish pharmaceutical prices were compared between Sweden and each country based on Swedish conditions with respect to pharmaceuticals and volumes. In that analysis, pharmaceuticals that Sweden uses a lot weigh heavily in the comparison. This means that Swedish prices may appear low because Sweden may have lower prices on the pharmaceuticals that the country uses a lot. However, this makes the comparison less relevant for the country of comparison because the domestic weights are more relevant. This section also includes the 'price baskets' of the comparison countries. Bilateral indices have been created based on each individual country's pharmaceuticals. An average of these indices has then been calculated. See Appendix 1 for a further description of the methodology. See also Appendix 3 for bilateral indices for each individual country.

The figure below shows a benchmark with a bilateral average of all countries' paired relationships in 2020.

Figure 21. Price comparison with bilateral average for pharmaceuticals without competition, 2020. Exchange rate is 3-year moving average.



Source: IQVIA and TLV analysis.

The figure above shows Sweden's relative price level for pharmaceuticals with and without competition, based on a bilateral average across all countries' 'price baskets'. For pharmaceuticals without competition, Sweden's prices are 4 percentage points lower than the average. This lands Sweden in ninth place on the list of the lowest prices of all 20 countries. This can be compared with the bilateral index with Swedish pharmaceuticals as a starting point in Figure 8. According to

this index, Sweden has the 6th–7th lowest prices. The changed ‘price basket’ thus makes Sweden’s prices appear slightly higher when other countries’ ‘price baskets’ are taken into account.

For pharmaceuticals with competition, Sweden has the lowest prices in 2020. This is no different from the bilateral index with Swedish pharmaceuticals as a starting point in Figure 14 above.

4 Discussion

For this report, analyses of Swedish pharmaceutical prices have been carried out for different segments and levels and been compared with 19 other European countries. The analyses cover the period from 2014 to 2020. In general, Swedish prices have fallen in relation to prices in other European countries. The prices of new pharmaceuticals in Sweden are in line with, or slightly lower than, other countries upon roll-out. During the period when pharmaceuticals are between 5 and 15 years old, Sweden's prices gradually increase compared with the average. For pharmaceuticals subjected to competition through the Product-of-the-month system, Sweden has the lowest prices among the countries compared. The declining relative prices have been a trend since 2016 and are primarily a result of the Swedish krona weakening in relation to the euro. The weakening Swedish exchange rate also impacts other areas, for example, the savings potential discussed in greater detail in the report on savings potential that TLV published in March 2020.[21]

For *pharmaceuticals without generic competition*, i.e. pharmaceuticals not covered by the Product-of-the-month system, Sweden lands in sixth place in 2020, where first place means the lowest prices, out of 20 countries in a bilateral comparison. The bilateral comparison compares prices in pairs for pharmaceuticals used in both countries. The placement is a move from ninth place in 2019 thanks to a relative price reduction of approximately 3.4 percentage points.[22] The relative price reduction is mainly driven by exchange rate fluctuations. The falling Swedish krona has contributed to pharmaceutical areas with previously high relative prices in Sweden compared with the rest of Europe now being at a similar or lower level than the European average price. For some pharmaceuticals, however, costs have decreased due to managed entry agreements. These pharmaceuticals are not included in the comparison above.

For pharmaceuticals without generic competition, spontaneous price competition between pharmaceuticals with a comparable or equivalent effect rarely arises on the Swedish market. The prices of these pharmaceuticals usually remain at the same level until the pharmaceuticals are either covered by regulated price reductions or an intervention from TLV or the regions. The rule-based price reductions include the 15-year rule, which reduces prices by 7.5 percent for products that have not been exposed to competition after 15 years, and the Product-of-the-month system. Historically, TLV's revies of price and reimbursement status in 2014–2017 led to significant price reductions and savings in benefits. From 2016, the regions have also, in connection with the price change applications, signed managed entry agreements with the companies on repayments for several pharmaceuticals, which has contributed to lower costs both through direct repayments and by reductions in official prices. Cost reductions in the form of repayments or discount systems are not visible in the comparison of public list prices.

[21] TLV (2020j).
[22] Measured as a cross-section index.

One example of an area with unchanged prices over time is NOAC for stroke prevention in patients with atrial fibrillation. In the Swedish market, there are four NOAC included in the benefits. The prices for the different pharmaceuticals are basically the same for all pharmaceuticals, and one of the pharmaceuticals represents 68 percent of all sales. Stronger price competition in that area could lead to lower prices and thus lower costs.

For *pharmaceuticals with competition*, i.e. pharmaceuticals covered by the Product-of-the-month system, Sweden has the lowest prices compared with the other countries in the comparison. The Swedish Product-of-the-month system has contributed to pharmaceuticals with competition making up around 60 percent of the sales volume, but only one-fifth of the sales value. Unlike pharmaceuticals without competition, the official pharmaceutical prices within the Product-of-the-month system can increase, which means that if the Swedish krona weakens, companies can raise prices to compensate for the loss due to the currency depreciation. We can see such a trend for Sweden from 2018 onwards.

The competition in the Product-of-the-month system is an effective way to take advantage of natural competition between medically substitutable pharmaceuticals. This has led to prices of pharmaceuticals included in the Product-of-the-month system being lower in Sweden than in countries with international reference pricing or in countries with weaker governance related to pharmaceuticals with the lowest prices. The Product-of-the-month system contributes to high transparency, which creates good conditions for competition.

For pharmaceuticals within the Product-of-the-month system, prescribers, patients, or dispensing pharmacists may oppose generic substitution at the pharmacy. In areas where a higher proportion of prescribers and/or patients reject substitution, competition tends not to lead to as much price pressure as in areas where a higher proportion is substituted at pharmacies.

In some areas, there are pharmaceuticals with generic competition without resulting in price competition. This applies, for example, in asthma/COPD where differences in inhalers prevent substitution or where prices have not been affected by the existence of generic alternatives or where there is generic competition. In the field of diabetes, there are biosimilar insulins, and price competition has not resulted in reduced prices of older pharmaceuticals, *inter alia,* because pharmaceuticals are sold with administration accessories that are not substitutable.

Sweden has relatively higher or rising prices of pharmaceuticals 5–15 years old, compared with the prices upon market entry and after patent expiry. This is structural and has nothing directly to do with the exchange rate. The *value-based pricing* applied in Sweden places high demands on follow-up to ensure a reasonable cost throughout the pharmaceutical's life cycle.

To manage pharmaceuticals that are 5–15 years old, reviews of price and reimbursement status and continuous health economic evaluation are important tools. For the years 2014–2017, TLV was commissioned by the government to lower the costs of preferential pharmaceuticals. This was accomplished primarily through TLV's review of pharmaceutical classes where there was no natural price competition despite a comparable effect between pharmaceuticals. From 2016,

reviews have been performed while regions and companies have signed managed entry agreements on repayments on pharmaceuticals already included in the benefits, which, together with reductions of the PRP, has led to reduced social costs for preferential pharmaceuticals. More than half of the more than three billion paid in repayments in 2019 comes from older pharmaceuticals, which were previously included in the benefits even without a managed entry agreement. Savings for these pharmaceuticals have been achieved through the regions' ability to negotiate with pharmaceutical companies and guide use towards pharmaceuticals with a lower price.

Compared with Sweden, several other countries similar to Sweden have lower prices on pharmaceuticals that are 5–15 years old. They have effectively introduced continuous price dynamics. Finland and France are countries where the prices of subsidised pharmaceuticals are processed systematically, for example, through temporary subsidies that are reviewed after a few years. In France, volume discounts are converted into list price reductions according to agreements with pharmaceutical companies, and there are also budget restrictions with repayments when a cost ceiling is exceeded. The clear rules that pharmaceutical prices will be adjusted appear to lead to lowered prices over time in these countries for pharmaceuticals that have been on the market for more than five years.

To create conditions for reasonable costs over time, product range, and early and equal access to new and innovative pharmaceuticals, competition in the pharmaceutical market needs to be stimulated. By creating a greater understanding of how the pharmaceutical market works, how pharmaceuticals are used, and what effect they have in everyday medical practice, there are better conditions for creating good competition. In addition, it is necessary to have knowledge and understanding of which pharmaceuticals are on the way and what future use will look like. Here, it is also important to work strategically with horizon scanning, to be able to look ahead and understand future pharmaceutical use, but also for diagnostics, medical technology, and other treatment methods.

To gain a better understanding and knowledge, both historically and in the current situation, it is important to have access to good data and methods to be able to evaluate the use and effect of pharmaceuticals. This is illustrated in TLV's work to develop, make available, and analyse data from clinical use and thereby develop value-based pricing.[23] Access to data is not only important to TLV, but also to, for example, companies and other authorities. The fact that all parties have access to the same information creates a solid foundation for effective competition. As the Swedish eHealth Agency and the National Board of Health and Welfare no longer disclose the same data on pharmaceutical sales as before, this limits the various stakeholders' access to reliable and comprehensive information. Lack of access to data also risks weakening the type of comparisons that TLV makes in this report in the long term.

In summary, it can be noted that Sweden's relative pharmaceutical prices are at their highest in areas where price competition does not arise and where other

[23] TLV (2020k).

countries lower the price even before patent expiry. Competition is a prerequisite for a long-term and sustainable financial system for pharmaceuticals. In practice, public authorities, regions, and private companies must cooperate.

Appendix 1: Sensitivity analysis and methodology

1 Sensitivity analyses

1.1 Currency exchange rate

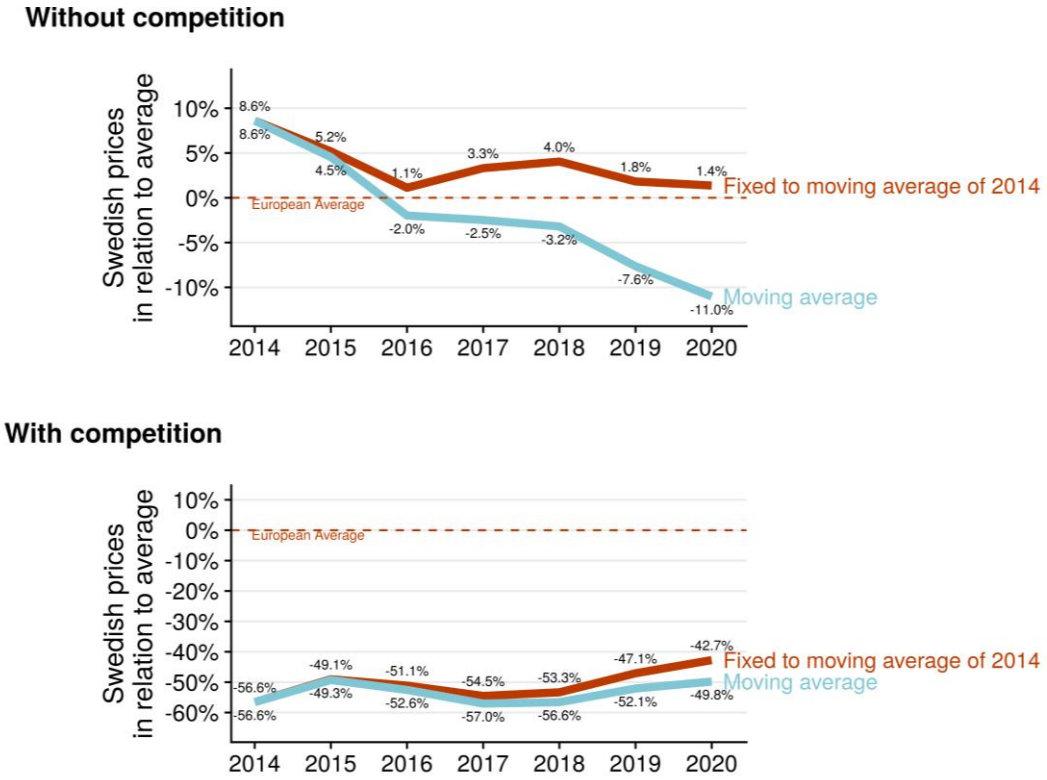
Currency fluctuations affect relative prices compared with other countries. If the currency strengthens in one country, prices in other countries appear to have fallen, even though they are nominally unchanged in each country's currency. A weaker Swedish krona, all other things being equal, means that Swedish prices appear lower compared to a scenario where the krona is stronger.

The exchange rate continues to be important for relative prices in the 2020 report, as the Swedish krona is currently weaker than it has been for a long time. During the first quarter of 2020, the krona weakened further against the euro, and this is a continuation of a trend that has been going on since 2014.

One way to show the importance of the currency for Sweden's relative price development is to fix the currency to what it was in 2014.[24] The figure below shows Sweden's relative prices of pharmaceuticals with and without competition between 2014 and 2020, divided by the rolling exchange rate and fixed to the moving average of 2014.

[24] Q1's three-year moving average exchange rate.

Figure 22. Sweden's relative prices compared with the yearly average as a cross-section. Pharmaceuticals without and with competition



Note: Exchange rate divided into 3-year moving averages each year and fixed 3-year moving average of 2014.

The figure above shows how Sweden's pharmaceutical prices developed between 2014 and 2020, depending on whether the currency was allowed to fluctuate over the years or was fixed at the 2014 exchange rate. Fixing the currency at the 2014 exchange rate means that all years are exchanged at the exchange rate that the Swedish krona had against the respective European currencies in 2014. For pharmaceuticals without competition with a moving exchange rate, Sweden's relative prices have gone from about nine percent above the average in 2014 to about 11 percent below the average in 2020. If, instead, the currency is fixed at the 2014 rolling exchange rate, Sweden's relative prices drop to just over one 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 one percent above the average for all countries.

1.2 Alternative price measures

Pharmaceutical use, both in terms of *which* and *how many* of the different pharmaceuticals are used in different countries, creates a complexity that must be considered when comparing prices between countries. In this report, a bilateral, so-called paired comparison is preferably used when comparing Sweden's pharmaceutical prices with prices in other individual countries. When the Swedish relative prices are put in relation to the European average, or over time, a cross-section index is most often used.

This section includes a comparison between individual countries, as a cross-section rather than a bilateral comparison. In cases where price information for a pharmaceutical is missing for a country, the European average price level for the pharmaceutical is used. Figure 23 shows a cross-section index for all countries. An index of 100 corresponds to average prices for all countries (European average).

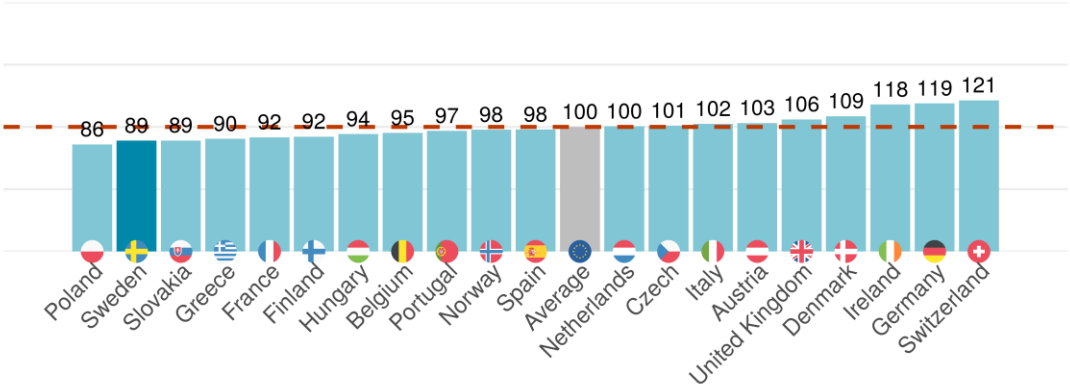
The selection of pharmaceuticals still includes those used in Sweden. However, the pharmaceuticals with low use in Sweden but a higher use in other countries are also included. The base is the average price level in Europe, with an index of 100. An index higher than 100 indicates a higher pharmaceutical price than the European average price. A pharmaceutical must be available in at least eight countries to be included in the comparison.

The method where the European average price is used if a country lacks a pharmaceutical can affect the rankings between countries. Countries with a low matching rate will, for example, have an index value where a major part of the underlying prices are not made up of the country's own prices but of imputed European average prices. This means that the ranking between countries in cross-section indices must be interpreted with caution. The cross-section index, on the other hand, is well suited for comparing Sweden's position in relation to the European average, for example, over time or with and without managed entry agreements.

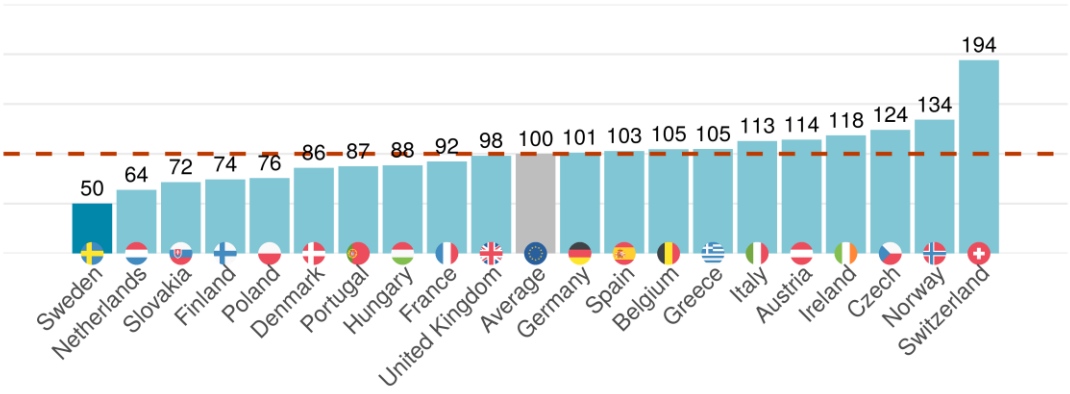
The differences in the method and the selection of pharmaceuticals result in Sweden receiving a relatively lower ranking compared with the bilateral comparison. It should be mentioned, however, that the selection of pharmaceuticals covered in the analysis are the pharmaceuticals used in Sweden and that the analysis is based on list prices that do not include any potential discounts.

Figure 23. Cross-section index, 2020. 3-year rolling exchange rate.

Pharmaceuticals without competition



Pharmaceuticals with competition



For pharmaceuticals without competition, Sweden has, according to the cross-section index, 11 percent lower prices than the European average. Sweden has the third lowest prices of the countries included in the comparison. This can be compared with the bilateral index where Sweden instead has the sixth lowest prices. As mentioned, however, the result in the cross-section index depends on the matching rate. For example, Portugal has higher prices than Finland according to the cross-section index (but not according to the bilateral index). This may be due to the low matching rate between Sweden and Portugal, which means that Portugal's prices in the cross-section index mainly consist of imputed European average prices.

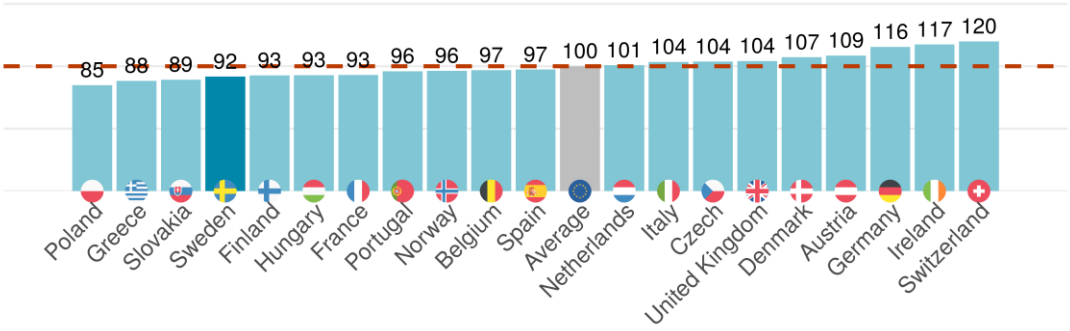
For pharmaceuticals with competition, Sweden has 50 percent lower prices than the European average. Sweden has the lowest prices of the countries included in the comparison. The placement is the same as in the bilateral index, although the difference compared with the other countries is greater in the cross-section index than in the bilateral index.

1.3 The effect of managed entry agreements

A common criticism of price comparisons at list prices is the existence of non-public (hidden) prices. In Sweden, there are managed entry agreements (*Managed entry agreements*) where pharmaceutical companies pay repayments to the regions for

part of the pharmaceutical costs. These repayment levels are confidential and can therefore not be compared or reported. The figure below shows the cross-section index for pharmaceuticals with the difference that all pharmaceuticals included in managed entry agreements in Sweden have been removed from the 'price basket' of pharmaceuticals.

Figure 24. Cross-section index for pharmaceuticals without competition and without managed entry agreement, 2020. 3-year rolling exchange rate.



Source: IQVIA and TLV analysis.

Note: Prices Q1 2020. Volumes running 12 months up to and including March 2019. 3-year average exchange rate. Excluding pharmaceuticals with managed entry agreements in Sweden. European average = index 100.

Figures 23 and 24 show that the countries' position and price level do not change significantly by excluding pharmaceuticals with managed entry agreements. When managed entry agreements are excluded, Sweden has 8 percent lower prices than the European average. This indicates that managed entry agreements in Sweden do not affect the general comparison of Sweden's pharmaceutical prices in relation to other countries.[25] By excluding pharmaceuticals assumed to have hidden prices to a similar extent as in Sweden, the comparison is based on pharmaceuticals with list prices, without discounts, to a greater extent. One disadvantage of excluding pharmaceuticals with a managed entry agreement is that just over 3 percent of pharmaceuticals are not included, which accounts for just under 23 percent of the sales value.

If pharmaceuticals covered by managed entry agreements in Sweden are excluded, the Swedish cross-section index amounts to 92, compared with 89 for pharmaceuticals without competition. This means that Sweden's relative price level is slightly lower for pharmaceuticals covered by managed entry agreements and slightly higher for pharmaceuticals not covered by managed entry agreements.

1.4 Purchasing Power Parity benchmark

The countries included in the report have a relatively large spread in Purchasing Power Parity (PPP) GDP per capita. Some countries may have almost three times more purchasing power than another.[26] Figure 25 shows how the ranking for all

[25] Other countries may have hidden actual prices for pharmaceuticals that do not have a managed entry agreement in Sweden, which means that prices in other countries may be lower. In Sweden, managed entry agreements provide a repayment, which means that the actual cost of pharmaceuticals is lower than at set price.
[26] This means that a country with high purchasing power can buy about three times as many goods for an average wage in its own country, compared to the country with lower purchasing power.

countries changes if prices are adjusted according to Purchasing Power Parity GDP level.

Figure 25. 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 competition, 2020.

Source: IQVIA, IMF and TLV analysis.

Note: Rank 1 means that the country has the lowest prices. Running 3-year average exchange rates per year.

The figure above shows major changes in position if PPP adjusted prices are used. Many of the countries with low relative pharmaceutical prices nominally end up with high relative prices if they are PPP adjusted. The same applies for the opposite. Ireland is in place 18 out of 20 with nominal list prices, which means high relative prices. If Ireland's prices are PPP adjusted, however, it appears to have the lowest prices in Europe. Greece, on the other hand, has the second lowest nominal relative prices, but appears to have the second highest relative prices if these are PPP adjusted.

2 Methodology and data

2.1 Segmentation depending 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 competition (outside the product-of-the-month system)

- Pharmaceuticals with competition (within the product-of-the-month system)

The segment Pharmaceuticals without competition includes pharmaceuticals where 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. The reason why these pharmaceuticals are included in the same segment is that the Swedish Medical Products Agency considers these pharmaceuticals as original pharmaceuticals and that pricing conditions will then be the same as for original pharmaceuticals. However, the competition conditions may differ between the countries included in the comparison. The segment Pharmaceuticals with competition (within the product-of-the-month system) includes all pharmaceuticals included in the generic substitution within the product-of-the-month system in March of each year up to and including 2020.

2.2 Dataset and selection of pharmaceuticals

The starting point in the analysis is prescription medicines in Sweden with the highest sales and covered by the benefits. In this year's dataset, the data has been supplemented with pharmaceuticals with the highest sales in Europe and new pharmaceuticals between 2015 and 2017 that were included in EFPIA's WAIT survey on time-to-market access in different countries.

Before TLV's first report in 2014, IQVIA[27] was commissioned to deliver data for 200 substances in the Patent-protected pharmaceuticals segment, 180 substances in the Unprotected original pharmaceuticals without competition segment, and 200 substances in the Unprotected pharmaceuticals with competition with the highest sales segment. Since then, the data has been updated each year and supplemented with new pharmaceuticals with high sales numbers.

Price indices presented in the study are based on list prices and on the pharmacies' wholesale price or equivalent. The reason why wholesale price is used as a price measure is that it does not include the pharmacies' trade margin, which may vary between countries depending on how the remuneration to the pharmacies is designed 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 potential 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 2020 - 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.

[27] Before November 2017, IQVIA was called IMS Health.

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

Table 2. Contribution margin ratio (of total sales)

Years	Total AIP IQVIA	Total AIP eHm	Contribution margin ratio
2014	4.13	4.54	91%
2015	4.74	4.78	99%
2016	4.68	5.04	93%
2017	4.74	5.35	89%
2018	5.75	5.72	101%
2019	6.05	6.16	98%
2020	6.52	7.26	90%

Note 1: Data from IQVIA in relation to data from the Swedish eHealth Agency (eHm). Sales of pharmaceuticals during Q1 between 2014 and 2020. AIP (wholesale price) level totals.

Note 2: Pharmacy preparations are not included in the comparison.

The sales value does not cover all sales of prescription medicines in Sweden in the outpatient care market as only the best-selling substances in Sweden and Europe are included.

In the price comparison, reconciled prices for different 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 package size, as package sizes vary 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 packages are normally sold in Sweden, compared with countries where collection takes place at more frequent intervals. If the package sizes frequently sold have a lower price than those with lower sales, this would mean that large packages 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 certain substance, dosage form, and strength. This means that different package sizes can be compared, and the price indices become more accurate. This approach increases the matching rate with other countries, even if the precision of the comparison is slightly lower than when matching at the packaging level.

One alternative would be to match at the packaging level, meaning the exact same package 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 packaging. At the same time, the risk is greater that a certain specific packaging is not available in many countries. Package size can often be linked to shipping frequency. The longer the time between dispatches, the likelier larger packages are common, 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 what a country pays to treat different diagnoses. The problem with such a price comparison is 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 information for the rolling 12 months up to and including March 2019 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:

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

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 stamp is replaced by country, abroad U and Sweden S.

The weight can either be sales volume abroad or sales volume in Sweden. The choice determines whether the price index shall 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. with the country as a base from which price differences shall be measured, in this case Sweden's:

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

Here, p^U refers to price abroad and q^S to quantity in Sweden. If the price is the same in Sweden and abroad, the index value is 100. If the index is <100 (or >100), this 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, for example, 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 (savings) 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 savings. The supply of pharmaceuticals, i.e. 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 respective period. Absolute price index numbers should 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, 2018, 2019, and 2020.

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. In Appendix 3, the weights of each country for different figures are presented.

2.5 Definition of price baskets

To calculate a price index, regardless of whether it is a bilateral or a cross-section index, a 'price 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-section indices require that the pharmaceuticals included in the comparison basket are used in at least 40% 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 price basket forming the base for the cross-section index is more limited compared with the bilateral basket, which is due to the fact that a price needs to be determined in all countries for the same basket. For those countries that do not use a certain 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. 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 3.3.3 is divided into effects of price and currency changes, respectively. The fact that the Swedish use is consistently used even in calculations of cross-sections for the

other countries means that the effect of a possible volume change, between countries and over time, is eliminated. This analysis is presented in sections 3.2.4 and 3.3.4.

The analysis is based on the average price level for pharmaceuticals used in Sweden throughout the period 2014–2020, weighted by the use of each pharmaceutical in 2014. This way, a weighted average price for each year's basket of pharmaceuticals is calculated:

Let the relative cost of pharmaceuticals b at the time t between country i and country j, at the exchange rate $\frac{c_i}{c_j}$, be calculated:

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

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

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

In the present analysis, Swedish volumes are used throughout to calculate costs in different countries. This 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 accounts for how the relative cost difference is calculated for a certain 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 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 similar to cross-sections. Each country's pharmaceuticals for each year are calculated in relation to the average for that pharmaceutical that year. Then these relative price levels are aggregated per pharmaceutical age in the base country only, weighted by sales amount. The data base for the figure thus 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 this uses multiple exchange rates for the same pharmaceuticals. 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 summary 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	**Substance**
ACE inh./ARB	Amlodipine, Valsartan, Candesartan Cilexetil, Candesartan Cilexetil, Hydrochlorothiazide, Enalapril, Enalapril, Hydrochlorothiazide, Eprosartan, Hydrochlorothiazide, Irbesartan, Hydrochlorothiazide, Losartan, Hydrochlorothiazide, Telmisartan, Hydrochalsinoprilipril, Telmisartan, Valsartan, Eprosartan, Hydrochlorothiazide, Hydrochlorothiazide, Olmesartan Medoxomil
ADHD	Atomoxetine, Guanfacine, Lisdexamphetamine, Methylphenidate, Dexamphetamine
Alimentary Tract and Metabolism	Agalsidase Alpha, Agalsidase Beta, Aprepitant, Carglumic Acid, Glycerol Phenylbutyrate, Glycopyrronium, Granisetron, Laronidase, Mercaptamine, Metoclopramide, Migalastat, Miglustat, Netupitant, Palonosetron, Nitisinone, Obetichansaproletapitride Acid, Obetichanetrolithapyride, Trientine, Misoprostol, Prasterone, Chenodeoxycholic Acid, Domperidone
Analgesics	Almotriptan, Codeine, Paracetamol, Dihydroergotoxin, Eletriptan, Fentanyl, Hydromorphone, Morphine, Naloxone, Oxycodone, Oxycodone, Rizatriptan, Sumatriptan, Tapentadol, Tramadol, Zolmitriptan, Dihydroergotamine, Ibuprofen, Morphotolamine, Paracetamine, Codeacetamine Papaverine, Phenobarbital, Scopolamine Methyl Hydroxide

Pharmaceutical Class	Substance
Anaemia	Darbepoetin Alfa, Epoetin Alfa, Epoetin Beta, Epoetin Theta, Epoetin Zeta, Methoxy Polyethylene Glycol-Epoetin Beta
Anaesthetics	Fentanyl, Lidocaine, Lidocaine, Prilocaine
Antibiotics and Chemo, Dermat.	Aciclovir, Fusidic Acid, Imiquimod, Ingenol Mebutate, Metronidazole, Mupirocin, Penciclovir
Anticoagulants	Acetylsalicylic Acid, Dipyridamole, Caplacizumab, Clopidogrel, Dalteparin Sodium, Dipyridamole, Enoxaparin Sodium, Fondaparinux Sodium, Iloprost, Prasugrel, Selexipag, Ticagrelor, Ticlopidine, Treprostinilic, Acinzapilyl, Tinzostaryl,
Antidiarrheals	Budesonide, Budesonide, Formoterol, Eluxadoline, Fidaxomicin, Hydrocortisone, Loperamide, Mesalazine, Morphine, Nystatin, Olsalazine, Prednisolone, Racecadotril, Sulfasalazine, Vancomycin, Rifaximin, Balsalazide
Antiepileptic	Brivaracetam, Cannabidiol, Tetrahydrocannabinol, Carbamazepine, Clonazepam, Eslicarbazepine Acetate, Ethosuximide, Felbamate, Gabapentin, Lacosamide, Lamotrigine, Levetiracetam, Oxcarbazepine, Perampanel, Pregababalidine, Acegabalin, Regabalin,
Antihypertensives	Amlodipine, Amlodipine, Hydrochlorothiazide, Olmesartan Medoxomil, Amlodipine, Hydrochlorothiazide, Valsartan, Atenolol, Betaxolol, Bisoprolol, Carvedilol, Diltiazem, Doxazosin, Felodipine, Isradipine, Lercanidipine, Metopipolol, Nopipolol, Nopipolol, Metoprolol, Hydralazine, Amlodipine, Valsartan
Anti-inflammatory and Anti-rheumatics	Celecoxib, Diclofenac, Diclofenac, Misoprostol, Etoricoxib, Ketoprofen, Naproxen, Penicillin V, Phenylbutyrate, Aurothiomalic Acid, Dexibuprofen, Nabumetone, Tenoxicam, Piroxicam Betadex
Antiparasitic	Artemether, Lumefantrine, Atovaquone, Proguanil, Mebendazole, Mefloquine, Metronidazole, Pentamidine, Atovaquone, Hydroxychloroquine, Tinidazole, Chloroquine
Antipsoriatics	Acitretin, Betamethasone, Calcipotriol
Blood Coagulation Factors	Albutrepenonacog Alfa, Damoctocog Alfa Pegol, Efmoroctocog Alfa, Eftrenonacog Alfa, Emicizumab, Eptacog Alfa (Activated), Lonoctocog Alfa, Moroctocog Alfa, Nonacog Alfa, Nonacog Beta Pegol, Octocog Alfa, Alfa, Rurioctoc Alfa, Rurioctoc Nonacog Gamma
Blood Substitutes and Perfusion Solutions	Iron Ferric
Cardiac Therapy	Amiodarone, Dronedarone, Etilefrine, Isosorbide Mononitrate, Ivabradine, Levosimendan, Lidocaine, Midodrine, Nitroglycerin, Propafenone, Ranolazine, Digoxin, Disopyramide, Flecainide, Lidocaine, Methylprednisolone, Mexiletine

Pharmaceutical Class	Substance
CGRP Inhibitor	Erenumab, Fremanezumab
Cholesterol-Lowering	Alirocumab, Atorvastatin, Atorvastatin, Ezetimibe, Bezafibrate, Colesevelam, Colestyramine, Evolocumab, Ezetimibe, Ezetimibe, Simvastatin, Phenofibrate, Fluvastatin, Gemfibrozil, Pravastatin, Rosuvastatin, Simvastatin, Colestipol
Contraceptives	Desogestrel, Dienogest, Estradiol, Dienogest, Ethinylestradiol, Drospirenone, Ethinylestradiol, Drospirenone, Ethinylestradiol Betadex, Ethinylestradiol, Levonorgestrel, Ethinylestradiol, Norgestimate, Etonogestrel, Levonorgestrel, Lynestyprone, Medesthenone
Corticosteroids, Dermat.	Betamethasone, Betamethasone, Clioquinol, Betamethasone, Salicylic Acid, Clobetasol, Clobetasone, Fluticasone, Mometasone, Fusidic Acid, Hydrocortisone, Hydrocortisone, Hydrocortisone, Oxytetracycline, Mometasone, Salicylotrone Acid, Betamethasone
Diabetes - Insulin	Insulin Aspart, 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 Lispro, Insulin Lispro, Insulin Lispro Protamine, Insulin Aspart, Insulin Aspart Protamine
Diabetes - Non-Insulin	Acarbose, Canagliflozin, Canagliflozin, metformin, dapagliflozin, dapagliflozin metformin, dapagliflozin Saxagliptin, Dulaglutide, Empagliflozin, Empagliflozin, Linagliptin, Empagliflozin, Metformin, Ertugliflozin, Ertugliflozin, Metformin, Exenatide, Glibenclamide, Glimepiride, Glipizide, Linagliptin, Linagliptin, Metformin, Liraglutide, Lixisenatide, Metformin, Metformin, Pioglitazone, Metformin, Saxagliptin, Metformin, Sitagliptin, Metformin, Vildagliptin, Pioglitazone, Repaglinide, Saxagliptin, Semaglutide, Sitagliptin, Vildagliptin, Ertugliptin, Ertugliptin, Ertugliptin
Diuretics	Amiloride, Hydrochlorothiazide, Bumetanide, Eplerenone, Furosemide, Hydrochlorothiazide, Hydrochlorothiazide, Quinapril, Spironolactone, Tolvaptan, Torasemide, Bendroflumethiazide, Bendroflumethiazide, Potassium, Metolazone
Gynaecological Agents	Bromocriptine, Cabergoline, Quinagolide, Metronidazole, Clindamycin
Hepatitis C	Daclatasvir, Dasabuvir, Elbasvir, Grazoprevir, Glecaprevir, Pibrentasvir, Ledipasvir, Sofosbuvir, Ombitasvir, Paritaprevir, Ritonavir, Ribavirin, Sofosbuvir, Sofosbuvir, Velpatasvir, Sofosbuvir, Velpatapvir, Voxilaprevir
HIV	Abacavir, Abacavir, Dolutegravir, Lamivudine, Abacavir, Lamivudine, Abacavir, Lamivudine, Zidovudine, Atazanavir, Bictegravir, Emtricitabine, Tenofovir Alafenamide, Cobicistat, Darunavir, Cobicistat, Elvitegrafen, Tentrovir, Emtricitabir,

Pharmaceutical Class	Substance
	Emtricitabir, Dolutegravir, Dolutegravir, Lamivudine, Dolutegravir, Rilpivirine, Doravirine, Lamivudine, Tenofovir Disoproxil, Efavirenz, Efavirenz, Emtricitabine, Tenofovir Disoproxil, Emtricitabine, Emtricitabine, Rilpivirroabinophenovinopine, Tenofoviropine, Tenofovir Lamivudine, Letermovir, Lopinavir, Ritonavir, Maraviroc, Nevirapine, Raltegravir, Rilpivirine, Ritonavir, Stavudine, Tenofovir Disoproxil, Zidovudine, Cobicistat, Darunavir, Emtricitabine, Tenofovir Alafenatamide, Ataz
Hypothyroidism	Levothyroxine Sodium, Liothyronine, Thiamazole, Propylthiouracil
Immunoglobulins	Palivizumab
Incontinence	Fesoterodine, Mirabegron, Oxybutynin, Solifenacin, Tolterodine, Darifenacin
Interleukin Inhibitors	Anakinra, Brodalumab, Canakinumab, Guselkumab, Ixekizumab, Risankizumab, Sarilumab, Secukinumab, Tocilizumab, Ustekinumab
JAK Inhibitors	Baricitinib, Tofacitinib
Laxantia	Linaclotide, Methylnaltrexone Bromide, Naloxegol, Prucalopride, Bisacodyl
MS	Alemtuzumab, Cladribine, Dimethyl Fumarate, Fampridine, Fingolimod, Glatiramer Acetate, Interferon Beta-1A, Interferon Beta-1B, Natalizumab, Peginterferon Beta-1A, Teriflunomide
Muscle Relaxant	Baclofen, Orphenadrine, Paracetamol, Caffeine, Orphenadrine, Propyphenazone, Chlorzoxazone
Neuroleptic	Alprazolam, Aripiprazole, Buspirone, Chlorprothixene, Clomethiazole, Clozapine, Dexmedetomidine, Diazepam, Flupentixol, Haloperidol, Hydroxyzine, Levomepromazine, Lorazepam, Melatonin, Melperone, Midazolam, Nitrapiperidine, Nitraperipidone, Zolpidem, Zopiclone, Zuclopenthixol, Cariprazine, Zaleplon, Lurasidone, Brexpiprazole, Perphenazine, Propiomazine
NOAC	Apixaban, Dabigatran Etexilate, Edoxaban, Rivaroxaban
Obstructive Airway Diseases	Aclidinium Bromide, Aclidinium Bromide, Formoterol, Bambuterol, Beclometasone, Beclometasone, Formoterol, Beclometasone, Formoterol, Glycopyrronium, Benralizumab, Budesonide, Budesonide, Formoterol, Ciclesonide, Fluticasone, Fluticasolicone Vilonate,, Fluticasone, Salmeterol, Formoterol, Glycopyrronium, Indacaterol, Indacaterol, Ipratropium Bromide, Ipratropium Bromide, Salbutamol, Mepolizumab, Montelukast, Olodaterol, Olodaterol, Tiotropium Bromide, Omalizumab,

Pharmaceutical Class	Substance
	Roflumamilinium, Saloflumilom,, Vilanterol, Formoterol, Glycopyrronium
Oestrogens	Estradiol, Estradiol, Nomegestrol Acetate, Tibolone, Estradiol, Medroxyprogesterone, Conjugated, Bazedoxifene, Estrogenic Substances
Oncology Not Protein Kinase Inh	Abiraterone Acetate, Anagrelide, Anastrozole, Asparaginase, Azacitidine, Bevacizumab, Bexarotene, Bicalutamide, Bortezomib, Brentuximab Vedotin, Buserelin, Busulfan, Cabazitaxel, Capecitabine, Carfilzomib, Cetuximab, Cribuxin, Chlorambine Estramustine, Etoposide, Etoposide Phosphate, Exemestane, Filgrastim, Fludarabine, Fluorouracil, Salicylic Acid, Fulvestrant, Gimeracil, Oteracil, Tegafur, Goserelin, Histrelin, Hydroxycarbamide, Idarubicin, Idelalisib-Alfa-Alferon, Interferon Alfera 2, Interferon Beta-1B, Irinotecan, Ixazomib, Lenalidomide, Lenograstim, Letrozole, Leuprorelin, Lipegfilgrastim, Medroxyprogesterone, Melphalan, Mercaptopurine, Methotrexate, Methyl-5-Aminolevulinic Acid, Mitotaban, Panivel, Nibaparan, Nivapar,, Pembrolizumab, Pertuzumab, Polyestradiol Phosphate, Pomalidomide, Tamoxifen, Temozolomide, Tipiracil, Trifluride ine, Topotecan, Toremifene, Trabectedin, Trastuzumab, Trastuzumab Emtansine, Treosulfan, Triptorelin, Venetoclax, Vinorelbine, Vismodegib, Tioguanine, Tipiracil
Ophthalmologicals	Acetazolamide, Aciclovir, Apraclonidine, Bimatoprost, Bimatoprost, Timolol, Brimonidine, Brimonidine, Brinzolamide, Brimonidine, Timolol, Brinzolamide, Brinzolamide, Timolol, Ciprofloxacin, Cromoglicic Acid, Dorzolopane, Dorzolaman, Pilocarpine, Pilocarpine, Timolol, Prednisolone, Ranibizumab, Tafluprost, Timolol, Timolol, Timolol, Travoprost, Travoprost, Verteporfin, Betaxolol, Emedastine, Moxifloxacin, Olopatadine, Tafluprost, Fusidic
Opioid Addiction	Buprenorphine, Buprenorphine, Naloxone, Methadone
Osteoporosis	Alendronic Acid, Clodronic Acid, Denosumab, Dibotermin Alfa, Ibandronic Acid, Pamidronic Acid, Risedronic Acid, Strontium Ranelate, Teriparatide, Zoledronic Acid, Calcium, Etidronic Acid, Alendronic Acid, Calcium, Colecalciferol
Other	Afamelanotide, Aflibercept, Alogliptin, Alprostadil, Aminosalicylic Acid, Asfotase Alfa, Atezolizumab, Autologous Limbal Stem Cells, Avelumab, Belatacept, Bezlotoxumab, Blinatumomab, Burosumab, Cangrelor, Chliponabonon, Allostonum, Delamanid, Diclofenac, Misoprostol, Durvalumab, Eliglustat, Elosulfase Alfa, Elotuzumab, emtricitabine, Rilpivirine, Tenofovir Alafenamide, Ethinylestradiol, Levonorgestrel, Ethinylestradiol, Norgestimate, Galcanezumab, Galsulfase, Gemtuzumab ozogamicin, Idarucizumab, Inotuzumab ozogamicin, Ipilimumab, Lanadelumab, Morphine, Necitumumab, Neratinib, Obinutuzumab, Ocrelizumab, Olaratumab,

Pharmaceutical Class	Substance
	Opicapone, Patisiran, Pegaspargase, Plerixafor, Ramucirumab, Ravulizumab, Reslizumab, Sebelipase Alfa, Silodosin, Siltuximab, Sugammadex, Susoctpoceclipa Alph, Cyclosilicate, Emtricitabine, Tenofovir Disoproxil, Tildrakizumab, Tisagenlecleucel, Cilostazol, Inhaler Device, Axicabtagene Ciloleucel, Benzydamine, Chloromethine, Dornase Alfa, Mecillinam, Ibuprofen, Paracetamol, Cenegermin, Methyl-5-Aminolevulinicabur, Methyl-5-Aminolevulinic Acid,, Ospemifene, T-Lymphocyte (Activated), Tasimelteon, Vestronidase Alfa, Padeliporfin, Levosulpiride
Other Antihemorrhagics	Eltrombopag, Romiplostim, Tranexamic Acid
Other Dermatologicals	Adapalene, Adapalene, Benzoyl Peroxide, Azelaic Acid, Brimonidine, Clindamycin, Clindamycin, Tretinoin, Diclofenac, Dupilumab, Econazole, Econazole, Triamcinolone Acetonide, Finasteride, Isotretinoin, Ivermectin, Tetimololone, Ketocolazole, Tetecolazole, Brimonidine, Brinzolamide, Bifonazole
Other Haematological	C1 Inhibitor (Human), Conestat Alfa, Icatibant
Other Immunostimulants	Peginterferon Alfa-2A, Peginterferon Alfa-2B, Peginterferon Beta-1A
Other Immunosuppressants	Azathioprine, Ciclosporin, Eculizumab, Leflunomide, Methotrexate, Mycophenolate Mofetil, Mycophenolic Acid, Pirfenidone, Sirolimus, Tacrolimus, Thalidomide
Other Musculo-Skeletal	Allopurinol, Ataluren, Febuxostat, Lesinurad, Nusinersen, Probenecid
Other Nervous System	Acamprosate, Betahistine, Buprenorphine, Naloxone, Cinnarizine, Dimenhydrinate, Disulfiram, Inotersen, Naltrexone, Pilocarpine, Pilocarpine, Timolol, Pitolisant, Pyridostigmine, Riluzole, Tafamidis, Varenicline, Ambenonium, Levomethadone
Other Respiratory	Acetylcysteine, Azelastine, Fluticasone, Beclometasone, Budesonide, Codeine, Dornase Alfa, Fluticasone, Fluticasone Furoate, Ipratropium Bromide, Ivacaftor, Ivacaftor, Lumacaftor, Ivacaftor, Tezacaftor, Mometasylpropanol, Cromog
Other Systemic Anti-infectives	Amphotericin B, Bedaquiline, Ethambutol, Fluconazole, Isavuconazole, Itraconazole, Micafungin, Posaconazole, Rifampicin, Voriconazole, Ethambutol, Isoniazid, Pyrazinamide, Rifampicin, Isoniazid, Rifampicin, Rifabutonium, Isavucutonium
Other Systemic Antivirals	Aciclovir, Adefovir Dipivoxil, Cidofovir, Doravirine, Entecavir, Etravirine, Famciclovir, Tenofovir Alafenamide, Tenofovir Disoproxil, Valaciclovir, Valganciclovir, Zanamivir
Other Systemic Hormonal Preparations	Betamethasone, Cetrorelix, Cinacalcet, Desmopressin, Dexamethasone, Etelcalcetide, Ganirelix, Glucagon, Hydrocortisone, Lanreotide, Mecasermin,

Pharmaceutical Class	Substance
	Methylprednisolone, Octreotide, Parathyroid Hormone, Pasireotide, Pegludinomecane, Pegvisinolone, Pegvisinolone
Others	Deferasirox, Deferiprone, Deferoxamine, Patiromer Calcium, Polystyrene Sulfonate, Sevelamer, Sucroferric Oxyhydroxide, Zirconium Cyclosilicate, Naloxone, Oxycodone
Otologicals	Hydrocortisone, Oxytetracycline, Polymyxin B, Ciprofloxacin
Pah	Ambrisentan, Bosentan, Macitentan, Riociguat
Parkinson's	Apomorphine, Benserazide, Levodopa, Biperiden, Bromocriptine, Carbidopa, Entacapone, Levodopa, Carbidopa, Levodopa, Entacapone, Pramipexole, Rasagiline, Ropinirole, Rotigotine, Safinamide, Selegiline, Tolcapone
Protein Kinase Inhibitors	Abemaciclib, Afatinib, Alectinib, Axitinib, Binimetinib, Bosutinib, Brigatinib, Cabozantinib, Ceritinib, Cobimetinib, Crizotinib, Dabrafenib, Dasatinib, Encorafenib, Erlotinib, Everolimus, Gefitinibatin, Ilitrinib, Loritinib, Osimertinib, Palbociclib, Pazopanib, Ponatinib, Regorafenib, Ribociclib, Ruxolitinib, Sorafenib, Sunitinib, Trametinib, Vandetanib, Vemurafenib
Proton-Pump Inhibitor	Esomeprazole, Lansoprazole, Omeprazole, Pantoprazole, Amoxicillin, Clarithromycin, Esomeprazole
Psychoanaleptics	Agomelatine, Amitriptyline, Bupropion, Bupropion, Naltrexone, Citalopram, Clomipramine, Donepezil, Duloxetine, Escitalopram, Fluoxetine, Galantamine, Idebenone, Maprotiline, Memantine, Mianserin, Mirtazapine, Moclobiligmine, Modafilemetraphine Vortioxetine, Desvenlafaxine, Nortriptyline
Sex Hormones	Choriogonadotropin Alfa, Corifollitropin Alfa, Cyproterone, Cyproterone, Ethinylestradiol, Estradiol, Norethisterone, Follitropin Alfa, Follitropin Beta, Follitropin Delta, Medroxyprogesterone, Norethisterone, Progesterone, Testosterone, Ulipristal Eestroglycetroline,
Stomatologicals	Triamcinolone Hexacetonide, Amphotericin B
Systemic Antihistamines	Bilastine, Cetirizine, Clemastine, Desloratadine, Ebastine, Fexofenadine, Loratadine, Promethazine, Alimemazine, Rupatadine, Meclozine, Dimenhydrinate, Promethazine, Thiourea
Systemic Antibacterials	Amoxicillin, Amoxicillin, Clavulanic Acid, avibactam, Ceftazidime, Azithromycin, Aztreonam, Cefadroxil, Ceftazidime, Ceftolozane, Tazobactam, Ceftriaxone, Chloramphenicol, Ciprofloxacin, Clarithromycin, Clindamycin, Colistin, Dalbavancin, Daptomycin, Doxycycline, Erythromycin, Flucloxacillin, Levofloxacin, Linezolid, Meropenem, Meropenem, Vaborbactam, Moxifloxacin, Nitrofurantoin, Pivmecillinam,

Pharmaceutical Class	Substance
	Sulfamethoxazole, Trimethoprim, Tedizolid, Telithromycin, Tobramycin, Trimethoprim, Lymecycline, Methenamine, Ciprofloxacin, Fluocinolicillin Acetone
TNF Inhibitors	Adalimumab, Certolizumab Pegol, Etanercept, Golimumab, Infliximab
TNF Inhibitors Alternative	Abatacept, Apremilast, Belimumab, Vedolizumab
Urologicals	Alfuzosin, Alprostadil, Dutasteride, Tamsulosin, Finasteride, Sildenafil, Tadalafil, Terazosin, Aviptadil, Phentolamine

Appendix 2 Price and subsidy systems in Europe

To contextualise the results of the price comparison, the following is a description of the subsidy and pricing systems of the participating countries.[28]

1 Sweden

TLV decides which pharmaceuticals to include in the benefit scheme. In 2019, the cost of pharmaceuticals within the benefits amounted to approximately SEK 31.9 billion, calculated on the basis of official PRP, including patient fees. The cost of prescription medicines outside the benefit scheme amounted to SEK 3.4 billion. In addition, the cost of pharmaceuticals for inpatient care, so-called requisition pharmaceuticals, amounted to SEK 9.9 billion.[29]

For pharmaceuticals without generic competition, value-based pricing applies.[30] For generics, the product-of-the-month system applies.

TLV's value-based pricing is based on three fundamental ethical principles:
1. the principle of human dignity - healthcare must respect the equal value of all human beings,
2. the principle of need and solidarity - those who have the greatest medical needs shall be entitled to more of the healthcare resources,
3. the principle of cost-effectiveness - the cost must be reasonable from a medical, humanitarian, and socio-economic perspective.

In order for a pharmaceutical to be subsidised, a pharmaceutical company must first submit an application to TLV for a subsidy. Thereafter, TLV assesses whether the cost is reasonable for the medicine to be included in the pharmaceutical benefits. The Board for Pharmaceutical Benefits, a decision-making body at TLV, makes the decision.

1.1 Managed entry agreements

A managed entry agreement is an agreement between the regions and the pharmaceutical company and may be one of several decision guidance documents in a matter before TLV. New pharmaceuticals are introduced earlier and earlier, and some pharmaceuticals are sometimes associated with uncertainties regarding use and effect in everyday medical practice. With managed entry agreements, the risk can be shared and enable early use, even when there is significant uncertainty about a pharmaceutical's medical effect and its cost-effectiveness.[31]

[28] For an in-depth study of the price and subsidy systems in Germany, France, and the United Kingdom, please see the 2018 report, TLV (2018).
[29] TLV (2020a).
[30] See for example TLV (2020e), TLV (2020f), and TLV (2020g).
[31] TLV (2020b).

Managed entry agreements can also be a tool for stimulating competition and reducing costs for pharmaceuticals already included in the benefits scheme. Such agreements are for example used when competition from generics or biosimilars do not lead to lower prices.

By the end of the first six months of 2020, there were 50 pharmaceuticals in outpatient care covered by relevant managed entry agreements. The total cost for the pharmaceutical areas where there are managed entry agreements is approximately 18 percent in wholesale price (AIP) of the total costs for pharmaceuticals included in the benefit scheme.[32]

Table 4. Pharmaceuticals for which there are or have been managed entry agreements

Area	Number of pharmaceuticals	Sales official prices (TSEK, PWP)
Cancer	15	2,169,598
CGRP inhibitors	2	142,649
Hepatitis C	11	867,259
Factor VIII	13	561,684
JAK inhibitors	2	219,660
PCSK9 inhibitors	2	100,802
TNF alpha inhibitors	10	1,707,166
Other	7	412,380
Total	50	6,181,197

Source: TLV (2020b), pp. 19–20.

Note: Statistics per area and total sales (official prices) June 2019 - May 2020, thousand SEK.

Most agreements exist in the areas of Cancer and Factor VIII. In the field of Cancer, new costly pharmaceuticals are often introduced at an early stage with a high degree of uncertainty.

1.2 High-cost protection

The cost of pharmaceuticals within the pharmaceutical benefit is included in the patient's high-cost protection. The patient pays a maximum of SEK 2,350 in patient fees for eligible pharmaceuticals per 12-month period. The regions cover the remaining part. The central government provides annual state subsidies to the regions for the costs of pharmaceutical benefits.

Since 2016, pharmaceuticals within the pharmaceutical benefit are free of charge for children under 18 years of age.

Since 1 January 2017, contraceptives within the pharmaceutical benefit are free of charge for young adults under 21 years of age.

1.3 Generic substitution

Generic substitution was established in Sweden in 2002 and, since 2009, TLV is responsible for the so-called product-of-the-month system (PV system), where

[32] TLV (2020b) p.8.

manufacturers compete on price through a monthly auction procedure. Generic substitution leads to lower prices and, eventually, major differences in price between substitutable pharmaceuticals may arise. If so, TLV lowers the highest accepted sales price within the benefits scheme by setting a lower ceiling price for substitutable pharmaceuticals. Every month, TLV analyses prices and sales volumes to find the groups where the criteria for determining the ceiling price are met. When the prices in a group of substitutable pharmaceuticals have fallen by at least 70 percent of the price before generic competition arose and when generic competition has been going on for at least six months, TLV sets a ceiling price. If the criteria are met, a ceiling price of 35 percent of the original product's original price is set.[33] By setting a ceiling price in this way, the differences in price between substitutable pharmaceuticals within the benefits scheme decrease, but the effect will also be even lower costs in addition to the effect of generic substitution.

The purpose of the substitution of pharmaceuticals at the pharmacy level is to keep society's costs for pharmaceuticals low. The products-of-the-month are the substitutable pharmaceuticals with the lowest price that pharmacies offer their customers when substituting pharmaceuticals. Each month, TLV selects the pharmaceutical 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 throughout the price period. The substitutable pharmaceutical with the lowest price may vary, which means that pharmacies can offer different pharmaceuticals at different times. TLV also selects two back-up products that pharmacies can switch to if the least expensive products are unavailable.

Some older pharmaceuticals have no or weak generic competition. This may, for example, be due to the fact that a generic pharmaceutical is not considered substitutable for the original pharmaceutical or that the pharmaceutical is a so-called biopharmaceutical. In January 2014, a price reduction was introduced for pharmaceuticals older than 15 years included in the pharmaceutical benefits scheme that lack or only have weak generic competition. The price reduction corresponds to 7.5 percent of the price applicable in October 2012.[34]

For non-preferential prescription medicines, free pricing applies. The patient either covers the entire cost themselves or, as in the case of, *inter alia*, anti-infective medicines, the regions cover the entire cost.

2 Finland

Finland applies informal reference pricing. Since 2014, the reference countries include EU Member States as well as Norway and Iceland. In addition to reference prices, therapeutic value, benefit, and price of similar products are taken into account.[35]

[33] TLV (2020h).
[34] TLV (2020i).
[35] HILA (2020).

2.1 Original pharmaceuticals: fixed-term benefits

When pricing new pharmaceuticals, the following factors are taken into account:

1) prices in Finland for the corresponding pharmaceutical preparation used to treat the same disease,
2) the prices of the pharmaceutical preparation in other countries within the European Economic Area (EEA),
3) the healthcare costs resulting from the use of the pharmaceutical preparation and the potential benefits with respect to the patient and the total costs in healthcare and social care,
4) the benefits and costs of other available alternative treatment options,
5) the funds available for compensation.

Research and development costs can also be considered in the price assessment.

For pharmaceuticals with new substances, price and subsidy are decided for a maximum period of three years. After that, the company needs to reapply for a pharmaceutical to be included in the benefits scheme. For other products, the decision applies for a maximum period of five years.[36]

2.2 Reference price groups with 'price of the period'

In Finland, there is a system of price bidding in reference price groups that has certain similarities with the product-of-the-month systems in the Netherlands, Sweden, and Denmark. In Finland, however, the supply period is three months instead of one month like in Sweden. The price of other substitutable pharmaceuticals in the substitution group can change during the three-month period.[37]

The system means that pharmaceuticals at the ATC-5 level (pharmaceuticals with the same substance) are divided into reference groups. A reference price group presumes that there is at least one generic, parallel imported or parallel distributed pharmaceutical. The bidding procedure is thus not only applied on generics but also on parallel traded pharmaceuticals.

For generic pharmaceuticals in Finland, the first subsequent product of an original pharmaceutical must be priced at least 50 percent lower than the original. The price of the subsequent generic pharmaceutical must not exceed the official price. For some products, the level is 40 percent. Furthermore, the price of the original must be reduced by 40 percent nine months after the arrival of generic competition in order to maintain its subsidy status.

Since 2016, pharmacies are obligated to inform customers in connection with dispensation of which pharmaceutical has the lowest price in the substitution group.

[36] Kela (2020c)
[37] COWI (2014), p.9.

Twenty-one days before the start of a new substitution period, Kela provides information to the pharmaceutical companies on the applicable price at the start of the three-month period. The reference price is calculated based on the pharmaceutical companies' price notifications. EUR 0.50 is added to the price of the product with the lowest price within each substitution group (substance and biological equivalent). The calculated reference price is a maximum price used to calculate the subsidy. If the pharmaceutical price is lower than the calculated price, the subsidy calculation is based on the price of the pharmaceutical.

For the first two weeks of the three-month period, the price set by Kela applies. However, a pharmaceutical company can adjust the price of the pharmaceutical in connection with the database being updated with a new publication of the price list. If the pharmaceutical is not within the benefit, the pharmaceutical company is free to set a price. On the other hand, the price of pharmaceuticals within the benefit scheme may not be higher than the price determined by the Pharmaceuticals Pricing Board.

Due to price competition, prices on many pharmaceuticals are changed two weeks after the reference prices becoming effective (the 15th day of January, April, July, and October). What usually happens is that products with a price above the reference price are lowered to the reference price level and that products with a price below the reference price are raised to the reference price level. In practice, this means a system with multiple '*products-of-the-month*'.[38]

2.3 High-cost protection

In Finland, the general rule is that all patients receive financial compensation for pharmaceuticals where the Pharmaceuticals Pricing Board has issued a decision on reimbursement status. The ceiling for patient fees amounts to EUR 572 per year. From 2016, a step was introduced in the deductible. This means that all patients over the age of 18 pay EUR 50 before any subsidy comes in.

There are three categories of pharmaceutical subsidies:

Table 5.Subsidy levels in Finland and share of benefit, 2019

	Subsidy level	Percentage of benefit	Illnesses
Basic reimbursement	40%	21%	
Lower special reimbursement	65%	24%	11 chronic diseases
Higher special reimbursement	100	43%	34 chronic diseases
(Other subsidies)		12%	

Source: Kela (2020a)

The basic reimbursement refunds 40 percent of the price of the pharmaceutical or the calculated reference price (21% of the benefit cost). The lower special reimbursement refunds 65 percent of the price of the pharmaceutical or the calculated reference price (11 chronic diseases) (24%). The higher special

[38] Kela (2018).

reimbursement refunds 100 percent (34 serious chronic diseases) (43%), but the patient pays EUR 4.50 for each dispensation. The remaining 12% of the benefit cost was for the payment of other subsidies.[39]

The service fee amounts to EUR 2.50 per prescription during the year in which a patient has exceeded the deductible ceiling.

3 Norway

In Norway, the price of outpatient pharmaceuticals is set in relation to the price level in other countries through formal reference pricing. In Norway, the Norwegian Medicines Agency regulates the ceiling price for prescription pharmaceuticals.[40] Norway's reference countries are Belgium, Denmark, Finland, Sweden, Ireland, the United Kingdom (NHS), Germany, the Netherlands, and Austria. The system was implemented in 2002. The calculation is made at wholesale price level. The ceiling price is set at the average market price for the product in the three countries with the lowest price and a fixed trade margin is added. The price of the same product is compared, and the comparison is made regardless of whether the product is marketed under different names in the reference countries. The calculation uses exchange rates for at least the last six months' average value, which is compiled by the Norwegian Riksbank.

The time for implementation of price reviews is determined in advance and takes place regularly, which means that price adjustments are made every month for specific ATC groups. It is also possible for companies to apply for a price review. The price for the 250 substances with the highest turnover is adjusted according to price changes in the comparison countries or in the event of major exchange rate changes, but no more than once in a 12-month period. These pharmaceuticals, which are subject to annual price revision, represent about 70-80 percent of the market.

3.1 Generics: Stepped price model with volume component

For generic pharmaceuticals, *trinnprismodellen* (the Norwegian stepped price model, a graded pricing system) was introduced in 2005 and regulates the pharmacies' maximum retail price.

The price is gradually reduced depending on sales volume.[41] When generic competition arises, the price of original pharmaceuticals is reduced by 35 percent upon patent expiry. The second step in the model occurs six months later. The maximum price is then 59 to 81 percent lower than the price of original pharmaceuticals upon patent expiry. The third step occurs 18 months after generic competition has arisen. The maximum price is then 69 to 90 percent lower than the

[39] Kela (2017) pp. 80.
[40] The Norwegian Medicines Agency (2020a).

[41] The Norwegian Medicines Agency (2020b).

price of original pharmaceuticals upon patent expiry. Substances with high turnover receive a larger price reduction.[42]

Table 6. Trinnprismodellen/ the Norwegian stepped price model

Sales before generic competition	Step 1 (immediately)	Step 2 (after 6 months)	Step 3 (at the earliest after 18 months)	
Under MNOK 100	35%	59%	Turnover> MNOK 15	69%
Over MNOK 100	35%	81%	Turnover> MNOK 30	88%
			Turnover> MNOK 100	90%

Source: The Norwegian Medicines Agency (2020b).

A system for determining the ceiling price and the Norwegian stepped price model applies to both parallel imported pharmaceuticals and directly imported pharmaceuticals.

Pharmacies can negotiate the purchase price with the manufacturer. In practice, generic pharmaceuticals are subject to negotiations. Negotiations on purchase prices for original pharmaceuticals are more limited.

Pharmacies shall offer the least expensive pharmaceuticals when there are several options available on the substitution list *(Byttelistan)*.[43] In the event that a patient rejects generic substitution, the patient will cover the added cost, making up the difference.[44]

3.2 H- prescription

In Norway, in addition to ordinary outpatient prescriptions, there are so-called H-prescriptions, which makes it possible to collect certain inpatient pharmaceuticals at regular pharmacies. The H-prescription system has been in place since 2006 and has been extended several times. There is a joint procurement organisation for inpatient products, Hospital Purchasing, whose function is similar to that of Amgros in Denmark with the aim of obtaining discounts on inpatient pharmaceuticals.

The goal of reducing costs has also led to Norway gradually transferring the purchasing and handling of certain pharmaceutical classes from outpatient care to inpatient care.

3.3 High-cost protection

In general, the subsidy rate is 61 percent of the pharmaceutical cost, but different conditions apply. The subsidy rate is 100 percent for children under the age of 16 and low-income pensioners, as well as for pharmaceuticals for the treatment of infectious diseases, such as Tuberculosis, Hepatitis C, and HIV. The patient pays a

[42] The Norwegian Medicines Agency (2015).

[43] The Norwegian Medicines Agency (2020d).
[44] The Norwegian Medicines Agency (2020c).

maximum of NOK 520 per prescription in patient fees. A ceiling for patient fees is set annually and amounts to NOK 2,460 for 2020.[45]

4 Denmark

In Denmark, free pricing is applied for list price at wholesale price level. This applies to both original pharmaceuticals and pharmaceuticals with competition. The price of pharmaceuticals is reported to the Danish Medicines Agency, which in turn publishes the sales price and the subsidised price. PRP is regulated through fixed service fees and percentage margin on wholesale price. In Denmark, however, it has become more common for pharmaceuticals to be acquired through Amgros, the hospital system's procurement organisation, and handled within the scope of inpatient care. Therefore, the role of free pricing for pharmaceutical prices has decreased.

4.1 Price is set every second week

Denmark has a substitution system similar to the Swedish product-of-the-month system. Pharmaceutical manufacturers can announce changes to prices and the product range as frequently as every fortnight. The product with the lowest price in each group automatically becomes the highest remuneration subsidised.[46]

4.2 Agreement with the manufacturers

For a number of years, the Danish Association of the Pharmaceutical Industry (Lif), the government, and the regions in Denmark have entered into agreements on price restrictions for pharmaceuticals. The current agreement is valid for the period 2019–2023. This means that the reference price model for list prices within inpatient care shall be recalculated, resulting in a price reduction of 12.5 percent over a four-year period.[47] The agreement also ensures that the price of new inpatient pharmaceuticals must not exceed the average price in Sweden, Norway, Finland, the United Kingdom, the Netherlands, Belgium, Germany, Ireland, and Austria. For outpatient care, there is a similar agreement between manufacturers, the government, and the regions. The current agreement is valid between April 2019 and March 2022. The agreement provides a ceiling for prices after market entry. In general, prices cannot be raised above the market entry price. [48]

4.3 High-cost protection

Pharmaceutical companies apply for benefit status with the Danish Medicines Agency.[49] Subsidy can be general or individual. Individual subsidy can be granted for pharmaceuticals without general subsidy. In those cases, a physician applies for a subsidy on behalf of the patient. The compensation is 80 percent of the price. The

[45] Helse Norge (2020).
[46] The Danish Medicines Agency (2020a).
[47] Ministry of Health and the Elderly (2019).
[48] Lægemiddelindustriforeningen Lif (2020).
[49] The Danish Medicines Agency (2020c).

general subsidy is a positive list and may be limited to an indication or patient group.[50]

General subsidy and patient fees amount to the following in 2020: 0 percent for costs up to DKK 995; 50 percent for costs between DKK 995–1,655; 75 percent for costs between DKK 1,655–3,590; and 85 percent for costs over DKK 3,690. The deductible amounts to a maximum of DKK 4,190 per year. Children under the age of 18 have different subsidy rates than adults.[51]

Since 2015, pharmacists can open up to seven pharmacies within a 75-kilometre radius. The purpose of the increase in the number of pharmacies is for patients to have higher accessibility to pharmacies.

5 Germany

In Germany, there is a price and subsidy system that combines free pricing, reference pricing, and value-based pricing. The reference price part is informal/supportive, and price information is collected at the 'actual' ex-factory level (before transport and other distribution costs and after discounts and repayments). The majority of Germany's population (90%) is covered by compulsory Statutory Health Insurance (SHI). Others are covered by private insurance. Private health insurance companies usually have the same products as SHI, but they have the option to limit or expand the benefits.

All approved pharmaceuticals entering the German market are included in 'sickness funds' unless they belong to a category not covered by law (e.g. OTC) or by a decision of the Federal Joint Committee (Gemeinsamer Bundesausschuss - G-BA). Patients are generally required to contribute to the cost of pharmaceuticals through a patient fee of 10% (minimum € 5 and maximum € 10 per prescription).

AMNOG - *Arzneimittelmarkt-Neuordnungsgesetz*, a legal act that entered into force on 1 January 2011, regulates the pricing of new pharmaceuticals. According to AMNOG, manufacturers freely set pharmaceutical prices upon market entry.[52] However, they must also submit documentation including the necessary information for assessment of the therapeutic benefit of the pharmaceutical. AMNOG states that G-BA shall make a formal assessment of the 'additional therapeutic benefit' of new pharmaceuticals. The price is subject to negotiation based on the estimated therapeutic benefit within twelve months after the product was rolled out on the German market. The additional therapeutic benefit is assessed against a suitable comparator (standard of care) within 6 months. Usually, IQWiG makes the assessment.[53] The decision on the additional therapeutic benefit is based on this assessment and the result of a public hearing after publication of the evaluation. G-BA's decision on additional therapeutic benefit determines the preferential price after the first year of free price formation. If the pharmaceutical

[50] The Danish Medicines Agency (2020d).
[51] The Danish Medicines Agency (2020e) The highest annual cost for children under the age of 18 is DKK 4,190. 60% subsidy for costs between DKK 0–995, 60% for costs between DKK 995–1,655, 75% for costs between DKK 1,655–3,590. 85% for costs over DKK 3,590.
[52] VFA (2020).
[53] Federal Institute for Drugs and Medical Devices, BfArM (2020).

has not shown any additional therapeutic benefit, the pharmaceutical is included in a reference price cluster. The manufacturer and the National Association of Statutory Health Insurance Funds (GKV-SV) negotiate a preferential price within six months on the basis of G-BA's decision. If the parties cannot reach an agreement, the price is determined through arbitration.

AMNOG's evaluation and price negotiation apply to all new pharmaceuticals with new active substances introduced on the German market after 1 January 2011. Exemptions are made for pharmaceuticals with annual sales within SHI below € 1 million. For orphan drugs, additional therapeutic benefit is assumed by virtue of approval for sale without reference to a suitable comparator in Germany as long as annual sales within SHI are less than € 50 million. When this threshold is exceeded, the orphan drug is evaluated, and price is renegotiated in the same way as all other pharmaceuticals.

Most generics and some other pharmaceuticals are included in G-BA's reference price cluster. These include pharmaceuticals (1) with the same active substance and similar use, (2) with comparable therapeutic or pharmacologically active substances (usually at ATC 4 level), and (3) with comparable therapeutic effect (usually used for solid combinations).

Pharmaceuticals in a reference price cluster are allocated a maximum benefit amount. If the price of the pharmaceutical exceeds the amount, patients make up the difference. Companies often lower their prices to match the maximum amount of compensation. If they do not, patients can ask their prescribers about alternatives.

Within the health insurance system, discounts on list prices are common, especially for generic pharmaceuticals. Individual health insurance funds can agree on discounts on the pharmaceutical company's list price via public procurement. The prices of pharmaceuticals administered to hospital patients are negotiated between pharmaceutical companies and hospitals, hospital chains, or group purchasing organisations, while the official price for outpatient care acts as a ceiling price.

The pharmaceutical companies offer a statutory discount of 7% on the list price for patented pharmaceuticals that are not classified into reference price groups. Discount is also available for generic pharmaceuticals. The discount is normally 6 percent for pharmaceuticals with competition unless the price is at least 30 percent below the reference price.[54]

In addition to the statutory discounts, GKV-SV negotiates a discounted price (*Erstattungsbetrag*) with the manufacturers. These negotiated discount prices can entirely replace the statutory discount. Prices and their discounts (statutory) are available in the German price database.[55] In addition to discounts negotiated by GKV-SV, local health insurance funds can negotiate additional discounts. This

[54] KBV (2020).
[55] Lauer-Fischer (2020).

occurs, for example, with respect to generic and diabetes medicines where competition is fierce. These discounts are not visible in the price database.

Substitution at the pharmacy is an important tool for keeping rising pharmaceutical costs down. Pharmacy staff shall change to a less expensive pharmaceutical with the same substance. If the patient's sickness fund has an agreement on a discount for a product with the same substance as the prescribed product, the pharmacy is obligated to provide the product to which the discount applies. In some therapeutic areas, however, substitution is not allowed (e.g. thyroid hormones, antiepileptics or pharmaceuticals for certain heart diseases). In all other cases, the prescriber can reject substitution on medical grounds.

6 United Kingdom

In the United Kingdom, almost all healthcare, including subsidising of pharmaceuticals, is provided via the public healthcare system. Healthcare is tax funded.

Pricing of new pharmaceuticals uses value-based pricing reminiscent of the Swedish system. Manufacturers are free to set prices upon market entry. The subsidy is regulated by a negative list of pharmaceuticals that may not be prescribed with a benefit. Most new pharmaceuticals are granted a full subsidy in connection with approval of market entry and price. For the medicine to be prescribed in larger quantities, however, a recommendation from NICE is required, and the price must be below the ceiling price that NICE determines in a health economic assessment. Upon market entrance, manufacturers may request that NICE evaluates the new pharmaceutical. When applying, they state a requested price. NICE conducts an evaluation using value-based pricing with the help of quality-adjusted life years (QALYs) and determination of ceiling prices.

If NICE deems the pharmaceutical to be cost-effective at the requested price, they are included in the NHS recommendations. The medicine must then be provided by the NHS at the requested price. The NHS constitution of 2012 grants patients a legal right to pharmaceuticals recommended by NICE. NICE recommendations take precedence over local or regional recommendations. If NICE has recommended a pharmaceutical, local or regional boards will not modify or change these. NICE recommendations must be incorporated into local or regional regulations within 90 days.

There is free generic pharmaceutical pricing in the United Kingdom. This applies provided that the pharmaceuticals are priced below the ceiling price applicable at the time of the original pharmaceutical's patent expiry. Generic prescription (INN) is optional, but widely used.

7 France

France has a compulsory state health insurance system. The national health insurance is the main payer of health care, including pharmaceuticals (to about 70 percent). Ninety-seven percent of the French have additional insurance that covers the remainder[56].

France has been applying formal/informal reference pricing since 2003. Prices (ex-factory) should be *close to* prices in the reference countries (Germany, Spain, Italy, and the United Kingdom). Reference price review is carried out every 60 months.

Pharmaceutical companies make price information available in other countries. The price determined is fixed for five years. Thereafter, the list price can be renegotiated. Reference pricing is not the main method at the time of renegotiation.

When a manufacturer wants to launch a subsidised pharmaceutical, it shall be evaluated by the Economic Committee for Health Care Products (*Comité Economique des Produits de Santé, CEPS*). The transparency commission of the French High Authority for Health (*Haute Autorité de Santé, HAS*) assess the therapeutic value of the pharmaceutical and the additional therapeutic value of the pharmaceutical compared with alternative treatments. The scale has four steps where 1 means great improvement, new therapeutic area, reduced mortality, and 4 no improvement. CEPS then negotiates a price with the manufacturer. Reference prices are only part of the assessment of the pharmaceuticals estimated at 1-3 (major-some improvement). Those pharmaceuticals are also subject to an HTA evaluation.

7.1 Pricing of older pharmaceuticals

France has a special system for pricing older pharmaceuticals, where it converts discounts into list price reductions.[57] The three-year framework agreement governing the negotiations between CEPS and the manufacturers has a Section 21, which states the following:

> At the end of a period of price guarantee [five years for innovative pharmaceuticals] or, by default, at the end of a period three years after the pharmaceutical has been registered [received benefit], CEPS will request a full or partial conversion of agreed discounts [*remise conventionelle*] granted under the Social Services Act, L. 162–18.

CEPS thus has a strong framework to lean on when negotiating with manufacturers. The procedure is as follows:

- Every year, the National Assembly defines a savings target for health expenditure, including a reduction in pharmaceutical prices.
- Given pricing rules and market dynamics, CEPS sends an agreement to the manufacturer to reduce the price of a pharmaceutical.

[56] HST (2015), p. 70.
[57] Jonathan Rodrigues, CEPS, has contributed data to the description of the French system, 2018-06-01.

- The manufacturer has one month to respond and may also request deliberations.
- The process continues until CEPS and the manufacturer have agreed on a new price.
- In the end, CEPS can unilaterally determine the price by law.

A pharmaceutical valued I-III on the ASMR scale has a price guarantee that the price will not be below the lowest price in France's reference basket. However, this does not mean that the price cannot change during the first five years.[58]

In France, generic pharmaceuticals are priced at least 60 percent lower than the original. The price of the original is reduced by 20 percent and 18 months later, the price is further reduced by 12.5 percent. Eighteen months after the original pharmaceutical's patent expires, the price of generic pharmaceuticals is reduced by another 7 percent.

Biosimilars are priced 40 percent lower than the biological original. The price of the biological original is reduced by 20 percent. After 18–24 months, the price is further reduced depending on the pharmaceutical's market share. A market share of 60–100 percent results in the price being reduced by 15 percent. A market share of 40–60 percent results in the price being reduced by 10 percent. A market share of 0–40 percent means that the price is reduced by 5 percent.

From 1 January 2015, generic prescription is mandatory. However, it is allowed to name a brand on the prescription in addition to generic prescription.

Subsidy rate depends on how the disease is classified: 100 percent subsidy for pharmaceuticals for severe chronic diseases, 65 percent subsidy for pharmaceuticals with great clinical efficacy for severe diseases, 30 percent subsidy for pharmaceuticals with minor clinical efficacy, and 15 percent subsidy for pharmaceuticals with weak clinical efficacy.

In France, there are discounts linked to growth similar to the Italian system. The discounts are not known in advance and are not included in the list price. There are also managed entry agreements linked to price, volume, and various risks. This means that the actual price deviates downwards from the list price after certain volume steps have been achieved for some pharmaceuticals.

8 The Netherlands

It is mandatory for those living and working in the Netherlands to have basic health insurance. The contents of this insurance are determined by the state and are the same for everyone. Most health care costs are covered by the basic health insurance, and it is funded by fixed insurance premiums paid by everyone over the age of eighteen. There are essentially two financial arrangements for health insurance: either the insurance company covers all costs upon collection of pharmaceuticals, or the policyholder pays out-of-pocket and submits a compensation claim at the end of

[58] One example is Opdivo, whose list price began to fall after just one year (CEPS 2018).

the insurance period. The state decides which pharmaceuticals are to be included in the benefits scheme, the Drug Reimbursement System (*Geneesmiddelenvergoedingssysteem (GVS)*). The Dutch Ministry of Health sets ceiling prices twice a year according to the Drug Price Act (*Wet Geneesmiddelen prijzen (WGP)*).[59]

Reference pricing regarding ceiling prices is applied to all pharmaceuticals in both outpatient and inpatient care. The Netherlands has Belgium, France, Germany, and the United Kingdom in its reference price basket. The government plans to replace Germany with Norway in the reference price basket, which is estimated to save EUR 160 million per year.[60] A price review is carried out every six months and considers price developments in the reference countries and exchange rate fluctuations.[61]

Internal reference pricing occurs every month. Subsidised pharmaceuticals are divided into 500 cluster groups. Pharmaceuticals are substitutable within these groups. Ceiling price applies: patients can choose a more expensive pharmaceutical but must then make up the difference.[62]

Post 2012, the Dutch Ministry of Health can still set a ceiling on pharmaceuticals but is not obligated to do so.[63] Since 2005, greater emphasis has been placed on health economic assessments for certain types of pharmaceuticals. The pharmaceuticals need to undergo a cost-effectiveness evaluation before a subsidy decision is made. Pharmaceuticals managed within outpatient care with an expected budgetary impact of more than EUR 2.5 million need to undergo a health economic evaluation.

8.1 Managed entry agreements

Risk-sharing agreements exist in the Netherlands. These pharmaceuticals are usually handled within inpatient care, even if risk-sharing agreements occur within outpatient care, for example, for Hepatitis C medicines. Since 2012, TNF-alpha inhibitors are only handled by inpatient care to be able to reduce pharmaceutical costs more effectively.

8.2 Generics

The insurance companies procure the '*product-of-the-month*' within different pharmaceutical classes through different procedures:

Disclosed preference policy (lowest published price at manufacturer)
Non-disclosed preference policy (lowest confidential price at manufacturer)

Insurance companies can choose to only subsidise the '*product-of-the-month*' at pharmacies. A pharmaceutical with the lowest price within the pharmaceutical class

[59] SFK (2017).
[60] Government of the Netherlands (2020)
[61] Medicijnkosten (2018).
[62] Government of the Netherlands (2020).
[63] There are several regulations in the Netherlands that aim to limit and control government spending on prescription pharmaceuticals. Medicines Price Act (Geneesmiddelenprijzen (WGP)) and the subsidy system (Geneesmiddelenvergoedingssysteem (GVS)).

becomes the ‘preferred product’. This applies for a fixed period of time, between 1 and 24 months. However, there are insurance companies that apply even longer periods. The insurance companies apply different variations of *preference policy* for preferred products, ‘product-of-the-month/or’. The only rule is that there are at least two products within the same pharmaceutical class with respect to substance, form, and strength.

Pharmaceuticals are prescribed generically. The pharmacist at the pharmacy where the pharmaceutical is collected decides which package is dispensed. The prescriber can cite medical needs and reject substitution. If a patient does not want the preferred product, they must pay the full cost, unless it is due to a special medical need.

The price of pharmaceuticals collected at pharmacies can vary depending on which insurance company the patient is affiliated with. Either the lowest price according to G-Standard or list price is applied, and the pharmacy receives a repayment/discount according to a special agreement between the insurance company and the manufacturer.[64]

9 Belgium

Original pharmaceuticals
Belgium has been applying informal/supportive reference pricing since 2001. The reference countries are the rest of the EU. The manufacturer is required to state the sales price (ex-factory) in other European countries where it is available. A national price comparison is made as a complement. The total economic impact of the pharmaceutical and the price level for similar pharmaceuticals in Belgium are also examined. The official price is a ceiling price for the manufacturer. Then, the maximum mark-up and margin of distributors and pharmacies are determined based on national regulation of both the percentage margin and the total maximum mark-up on the purchase price of distributors (wholesalers) and at the pharmacy level.

9.1 Generics

Price control also applies to generic pharmaceuticals in Belgium. The price is immediately lowered when generics enter the market (in a reference cluster). The highest price for a generic product may not exceed the price of the most expensive product in the same reference cluster. For the first generic product, the price is set 43.64 percent lower (without reference cluster), or 51.52 percent lower (ex-factory), depending on the subsidy category.

For generic prescription, the substitution offered at the pharmacy is the least expensive option for pharmaceuticals included in the reference price system.

[64] Ruggeri, K. and Nolte, E. (2013).

Pricing of combination medicines (pharmaceuticals with more than one active substance) was adjusted in March 2017. Combination medicines whose patents have expired, but that are not included in the benefit scheme, are reviewed when one of the active substances in the combination medicine is included in the benefit scheme. The price and subsidy level of the combination medicines can never exceed the sum of the corresponding mono-substances.

Managed entry agreements exist for a large number of innovative new pharmaceuticals.

10 Austria

In Austria, formal reference pricing is applied. Price information is collected at ex-factory level. Outpatient pharmaceuticals within the benefit are subject to national price controls at distributors' purchase price. Prices are reviewed 18 months after a pharmaceutical enters the market, with additional follow-ups 24 months after the first price revision and possibly 18 months after a second price revision.[65]

The price is determined after price negotiations between the manufacturer and the Federal Ministry of Health (BMG) in consultation with the national Pricing Committee. In the negotiations, the average price in the EU is a ceiling price. To calculate the average price, the manufacturer needs to provide information on whether the pharmaceutical is available in other EU markets and list the prices in these countries.

Pharmaceuticals are categorised into different colour schemes for benefits: green, orange, yellow, and red. For pharmaceuticals in the green category, the price must be less than the average price in reference countries. For the yellow and red categories, the price must be less than or equal to the average price in the reference countries. Pharmaceuticals considered to provide additional benefit, as well as essential pharmaceuticals, fall into the dark yellow category. To calculate a reference price, price information needs to be available in at least two other countries. Statutory discounts, for example, in Germany, Ireland, and Greece, are taken into consideration. The average exchange rate is calculated based on the last month.

Generics

Since April 2017, a distinction is now made in Austria between subsequent generic products and biosimilars in terms of how prices are adjusted after new competitors enter the market. Previously, rules for generic pharmaceuticals also applied to biosimilars.

The price of the original product is reduced by 30 percent within three months of a first generic entering the market in order for it to maintain its preferential status. The first subsequent product is priced at least 50 percent lower than the original's reduced price. The second subsequent product is priced 18 percent lower than the first successor. If a third subsequent product enters the market, its price is set 15

[65] Vogler et al (2019), p. 2.

percent lower than the second successor. Thereafter, all comparable products need to have the same price level as the third subsequent product within three months.[66]

For biosimilars, the price of the original product is reduced by 30 percent after the first biosimilar has entered the market in order for the original to maintain its preferential status. The first biosimilar is priced at least 38 percent lower than the biological original's reduced price. The price of the second subsequent biosimilar is set 15 percent lower than the first successor. If a third subsequent biosimilar enters the market, its price is set 10 percent lower than the second successor.[67]

The price for the third generic product or biosimilar applies to both original and subsequent products in order for the products to maintain the preferential status.

Patients pay a fee per prescription upon collection. The fee is adjusted annually and amounted to EUR 6.10 in 2019. Patient fees can amount to a maximum of 2 percent of a patient's annual income.

11 Ireland

Framework agreement
On 20 July 2016, the Irish Government and the Irish Pharmaceutical Healthcare Association (IPHA) signed a new framework agreement on the supply of pharmaceuticals, valid from 1 August 2016 until 31 July 2020.[68] Thirty-eight pharmaceutical companies are part of IPHA.

Under the agreement, Ireland applies reference pricing. The manufacturer's price is set according to a currency-adjusted average price in reference countries (ex-factory). According to the agreement, the price of pharmaceuticals is set annually based on the average price in 14 reference countries (Belgium, Denmark, Finland, France, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, the United Kingdom, Sweden, Germany, Austria).[69]

Prices are reviewed every year, and reference pricing is the main criterion. Exchange rate fluctuations are also considered in the price review. Prices are only adjusted downwards.

The agreement also establishes that the discount (*PCRS (Community Schemes) Rebate)* on pharmaceuticals at present (2019) amounts to 5.5 percent in sales value. The agreement also stipulates a new discount for inpatient pharmaceuticals, which currently amounts to 5.5 percent.

11.1 Generics

Ireland has introduced generic substitution at ATC-5 level and reference pricing in order to reduce the total cost of pharmaceuticals.

[66] Vogler et al (2019), p. 11.
[67] Vogler et al (2019), p. 11.
[68] IPHA (2020a) The agreement continues to apply after July 2020.
[69] IPHA (2020a).

In Ireland, generic pharmaceuticals are priced 50 percent below the price of original pharmaceuticals. When a generic pharmaceutical enters the market, the price of the original pharmaceutical must be reduced by 30 percent within 60 days and by another 20 percent the following year.

Biopharmaceuticals (*Patent-Expired Non-Exclusive Biologic Medicines*) are priced 20 percent below the previous price of the biological original. When a biosimilar enters the market, a discount of 12.5 percent shall apply on the reduced price.[70]

There are essentially four benefit schemes.[71]

- General Medical Services (GMS) – EUR 1.50 in patient fees per product and EUR 15 per family and month.
- Drugs Payment Scheme (DPS) - ceiling for patient fees amounts to EUR 114 per month.
- Long-Term Illness Scheme (LTI) - 16 illnesses have special coverage. The subsidy level is 100 percent.
- High Tech Scheme (HT) - high-tech pharmaceuticals prescribed in hospitals but collected at pharmacy.[72] Examples include anti-rejection medicines (immunosuppressants) and pharmaceuticals used in connection with chemotherapy or growth hormones. Patient fees amount to EUR 62.03 when pharmaceuticals are collected at pharmacy and EUR 30.26 in the months when no pharmaceuticals are collected. Patients who collect pharmaceuticals for conditions that are part of LTI are exempt from patient fees. The same applies for pharmaceuticals within High Tech. For others, a ceiling on patient fees (the deductible) applies according to DPS in the amount of EUR 134 per month.

The 100 percent subsidy level applies after a special direct payment has first been made.

12 Italy

In Italy, prices are negotiated in a contractual process between manufacturers and a price committee (AIFA). Upon entering the market, a manufacturer presents AIFA with documentation. The Scientific Technical Advisory Committee (CTS) then makes a binding statement on the therapeutic value of the medicine and whether the medicine is innovative. The matter then goes to the Pricing and Reimbursement Committee (CPR), which evaluates the data and makes an agreement with the manufacturer. In the contractual process, the following criteria are taken into account:[73]

- Cost-effectiveness of the pharmaceutical in the absence of other effective therapies,
- Risk/benefit compared with alternative pharmaceuticals for the same indication,

[70] Section 8.1.3 of the Framework Agreement (IPHA (2020)).
[71] HSE (2020).
[72] IPHA (2020b).
[73] AIFA (2020a).

- Therapeutic cost per day compared to products with the same effect,
- Assessment of economic impact on the national health care system,
- Price and usage data for other European countries.

Reference price information is collected at ex-factory level. Reference price review is carried out every 24 months. Reference prices are supportive.

It is possible for pharmaceutical companies to apply for premium prices for innovative products. The result is announced in the *Gazzetta Ufficiale*.

Italy has implemented far-reaching decentralisations of responsibility for the healthcare sector, and regionalisation began in 2001. The different regions of Italy have the freedom to determine levels of patients' deductibles and can thus control their costs and budget outcomes.

Patient fees vary between regions (from EUR 1 to EUR 8). There is no percentage subsidy rate.

In Italy, generic pharmaceuticals are priced at least 20 percent lower than the reference price of the original medicine.[74]

In Italy, generic prescription is mandatory. Pharmaceutical names may only be used if there are special medical reasons.

13 Portugal

Portugal applies formal reference pricing. Spain, France, Italy, and Slovenia are reference countries. Price information is collected at ex-factory level. Reference price review is carried out every 12 months.

13.1 Subsidy rates

The subsidy rate is 100 percent on pharmaceuticals for certain defined diseases, such as HIV, Alzheimer's. For other prescription medicines, 90 percent subsidy for critical pharmaceuticals for chronic illnesses applies, 69 percent subsidy for critical pharmaceuticals for *serious* illnesses, 37 percent subsidy for non-priority pharmaceuticals with therapeutic benefit, and 15 percent subsidy for new pharmaceuticals with undetermined therapeutic benefit.

13.2 Generics

In Portugal, generic pharmaceuticals are priced up to 50 percent lower than the original. If the price of the reference product is below EUR 10, generic pharmaceuticals are priced 25 percent lower than the original.[75]

A new law on generic prescription entered into force in 2015.

[74] AIFA (2020b).
[75] Infarmed (2019).

14 Switzerland

Switzerland applies formal reference pricing in combination with value-based pricing ('national therapeutic comparison'). The average value of pharmaceutical prices in nine reference countries is used. Price information is collected at ex-factory level.[76] In 2015, the number of reference countries was increased from six to nine when Belgium, Finland, and Sweden were added.[77] Other countries include Denmark, the Netherlands, France, Germany, the United Kingdom, and Austria. Countries deemed similar to Switzerland in terms of economic conditions and treatment traditions were selected. Reference price review is carried out every 36 months.

Swissmedic handles market approval and the Federal Office of Public Health (FOPH) handles subsidy and pricing. When submitting an application to FOPH, pharmaceutical companies need to present a positive recommendation from Swissmedic. Price is decided in the List of pharmaceutical specialties (SL).[78] The conditions for the SL list includes that Swissmedic has approved the pharmaceutical and that it is deemed to be cost-effective. In the cost analysis, international reference prices are assessed, and a therapeutic comparison is made with similar products. This involves a comparison with other products that already have subsidy status in Switzerland for the same or a similar indication, a comparison of treatment cost per day, or total treatment cost. There is also an innovation bonus (for better effect, fewer side effects) of 1–20 percent that may be added in the therapeutic comparison.[79]

The price is weighted together with 2/3 of the weight according to the average international reference price and 1/3 of the weight for national therapeutic comparison. There is a limit of five percent if the national therapeutic comparison generates a higher value than the international reference price. In the absence of information on the international reference price (for example, if the pharmaceutical is not available on the market in other countries), only the national therapeutic comparison is used.

The pharmacy margin is regulated and is CHF 4–240 for prescription medicines, with an added percentage margin of 0–12 percent to the ex-factory price.

The price of generic pharmaceuticals shall be at least 20 percent lower than the price of the original.[80] Exceptions apply to generic pharmaceuticals with a small market share. The ceiling price for generic pharmaceuticals varies depending on the original pharmaceutical's sales four years before patent expiry. The price of the first subsequent product is set at least 10 percent lower than the original price if the original sales value was less than CHF 4 million. If the original's sales value was CHF 4–8 million, the price is set 20 percent below the original's. If the original's sales value amounted to CHF 8–16 million, the price is set 40 percent lower than

[76] FOPH (2016a).
[77] Interpharma, Price comparison with other countries.
[78] FOPH (2016b).
[79] FOPH (2016a).
[80] FOPH (2016a).

the original. If the sales volume amounted to between CHF 16–25 million, the price is set 50 percent lower than the original. If the sales value exceeded CHF 25 million, the price of the subsequent product is set 60 percent lower than the original.

The price of biosimilars is set 25 percent below the price of the original pharmaceutical.

Switzerland plans to introduce a reference price system for generic pharmaceuticals as well, but it has not yet been determined when.

Private health insurance is mandatory for all residents in Switzerland. The insurance covers, *inter alia*, the cost of pharmaceuticals prescribed by physicians. Patient fees amount to CHF 300 yearly. An additional 10 percent of the remaining cost, amounting to a maximum of CHF 700 annually, will be added. If a generic alternative to the pharmaceutical exists, but is not selected, the patient's additional cost instead amounts to 20 percent of the remaining cost of treatment.

15 Spain

Spain applies informal/supportive reference pricing based on the lowest price. Reference price review is carried out every 12 months. Price information is collected at ex-factory level.

Spain has implemented far-reaching decentralisations of responsibility for the healthcare sector. The Spanish regions have full budgetary responsibility for healthcare. The price in Spain shall be lower than the lowest price in the Eurozone when cost-effectiveness is deemed less favourable or when a pharmaceutical is deemed to have a major budgetary impact.[81]

Prices of generic pharmaceuticals are set 40 percent lower than the price for originals. When a reference cluster group is created, the original price is lowered to the same level as subsequent products.

Generic prescription is encouraged in Spain. Substitution with the pharmaceutical with the lowest price within the group shall be offered at pharmacy in all cases of generic prescription.

For pharmaceuticals not included in the reference price system, there are mandatory discounts. These amount to 7.5 percent for original pharmaceuticals, 4 percent for orphan drugs, and 15 percent for pharmaceuticals older than 10 years and without generic competition. Official list prices must consider this discount. At the same time, a 30 percent price reduction on generic pharmaceuticals was implemented.[82] There is a discount system linked to the size of pharmaceutical companies' investments in research and development in Spain.

[81] Ruggeri, K. and Nolte, E. (2013).

[82] MSCBS (2019).

16 Greece

Greece applies formal reference pricing. Price (ex-factory) is based on the average price for the two countries with the lowest price within the Eurozone. Since 2016, a price review is carried out twice a year, in May and in November. Decisions on new products are made four times a year.

Pricing for generic pharmaceuticals has changed several times in recent years. Since April 2016, the price of generic pharmaceuticals is linked to the price of original pharmaceuticals after patent expiry. Generic pharmaceuticals are priced 65 percent lower than the corresponding product with a reference price.

From August 2015, generic prescription is mandatory. Prior to 2016, the patient covered the entire cost exceeding that of the less expensive pharmaceutical (reference price) per therapeutic reference price group. Since 2016, patient and industry share the cost. A restriction has also been introduced where the patient pays a maximum of EUR 20 extra per pharmaceutical. Previously, the limit was EUR 50 extra per pharmaceutical.

Subsidy rate depends on illness: 100 percent subsidy for pharmaceuticals for serious illnesses and 90 percent subsidy for pharmaceuticals for chronic conditions and pharmaceuticals for low-income pensioners. There is also an ordinary compensation level of 75 percent.[83]

17 Hungary

In Hungary, formal reference pricing with the lowest price out of 31 countries (EU and EEA) is applied. Price information is collected at ex-factory level. The intention is to conduct an annual reference price review for the products with the highest sales within the benefit system, but this has not yet been implemented.

For generic pharmaceuticals in Hungary, the first subsequent product is priced at least 40 percent lower than the original. The second subsequent generic product is priced 20 percent lower than the first subsequent product. The third subsequent product is priced 10 percent lower than the second subsequent product. The fourth to sixth subsequent products are priced five percent lower than the previous. Thereafter, subsequent products are only priced lower than the previous one, without a specified minimum level. For biopharmaceuticals, the first subsequent product is priced 30 percent lower than the reference pharmaceutical and the second and third product 10 percent lower.[84]

The subsidy rate is 80 percent, 55 percent, and 25 percent depending on the therapeutic value and severity of the disease. For certain specific diseases, there is another subsidy ladder up to 100 percent.

[83] Greek Ministry of Health (2019).
[84] Kawalec et al (2017).

18 Czech Republic

In the Czech Republic, formal reference pricing is applied for both subsidy and pricing. The entire EU, with the exception of Bulgaria, the Czech Republic, Estonia, Italy, Germany, Austria, Romania, Greece, and Cyprus, are reference countries.[85] The average for the three countries with the lowest price is the reference price.

For a subsidy decision, if the pharmaceutical is to be included in the benefit scheme, the lowest price is calculated among the reference countries. If the lowest price is more than 20 percent lower than the second lowest price, the average of the second and third lowest price is calculated. Price information is collected at ex-factory level. When setting the price, the average of countries with the three lowest prices is calculated. The price is a ceiling price. Reference price review is carried out every 36 months.

Pharmaceuticals deemed 'very innovative', can receive a temporary subsidy for two years, and the period may be extended by one year. The pharmaceutical needs to have sufficient benefit and already have achieved subsidy status in at least two of the reference price countries. The average price for these countries is used to calculate a price.

For generic pharmaceuticals in the Czech Republic, the first subsequent pharmaceutical is priced 40 percent below the original price (30 percent for biopharmaceuticals). The same minimum price reduction is applied to the entire reference group.

Patient fees amount to the difference between the official subsidised price and the sales price. The patient also pays a dispensing fee for the prescription in the amount of CZK 30 (approximately EUR 1.2).

From 2018, electronic prescriptions (ePrescriptions) are mandatory.

19 Slovakia

In Slovakia, formal reference pricing is applied. The reference price is the average price for EU countries. When the change in pricing was introduced in 2008, the price was compared with the six countries with the lowest price in Europe. Since 2011, prices are calculated as an average of three of the countries with the lowest price for a product.[86] Reference price review is carried out every 6 months. Price information is collected at ex-factory level.

Pharmaceuticals classified as new and innovative undergo health economic evaluations with a ceiling price according to quality-adjusted life years (QALY). The limit is set at average annual earnings in Slovakia over the past two years.

Subsidy rate is either 100 percent or partial.

[85] SÚKL (2017).
[86] Psenkova et al (2017).

Generic prescription has been mandatory since 2011. Pharmacies are obligated to provide information upon dispensation on the pharmaceutical with the lowest price within the substitution group. For generic pharmaceuticals in Slovakia, the first subsequent pharmaceuticals are priced at least 35 percent lower than the original (at least 20 percent for biosimilars).

20 Poland

In Poland, informal/supportive reference pricing is applied using prices from 31 countries (EU and EFTA). Price information (ex-factory) is used in connection with the Economic Commission's price negotiation. Reference price review is carried out every 24 months. Poland has six countries that constitute a reference group in the HTA assessment (Estonia, Latvia, Lithuania, Hungary, Croatia, and Slovakia).

Every two months, the Polish Ministry of Health publishes a list of subsidised pharmaceuticals. Depending on whether the duration of treatment is longer or shorter than 30 days, the general subsidy rate for preferential pharmaceuticals is either 50 percent or 70 percent. The subsidy rate is 100 percent for certain diseases and also especially for veterans of war. Patient fees for certain pharmaceuticals (defined on *S-list*) used by retirement pensioners over the age of 75 were removed on 1 September 2016.

For generic pharmaceuticals, subsequent pharmaceuticals are priced at a maximum of 75 percent of the reference price for the original. The first price decision is valid for two years, thereafter for three- and five-year periods.

Appendix 3: Country-specific figures

This appendix provides figures that describe price levels and price development for all 20 countries in the study.

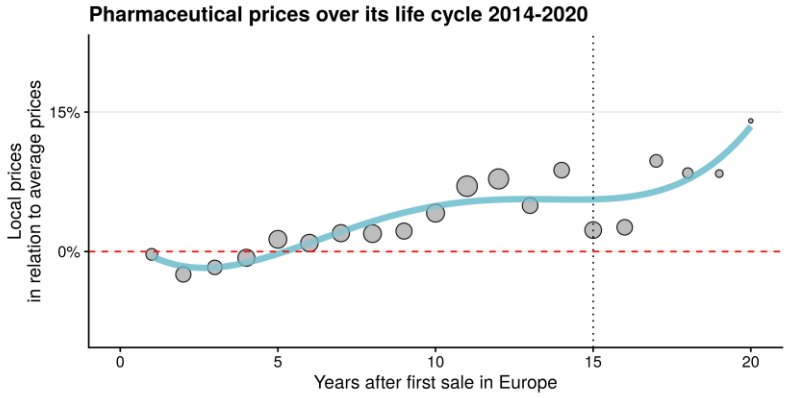
The top figure on each sheet shows a country's drug prices for every year after first sales in Europe, compared with the average in the compared countries (up to 20 years after first sales). Compare to Figure 4 in the main report.

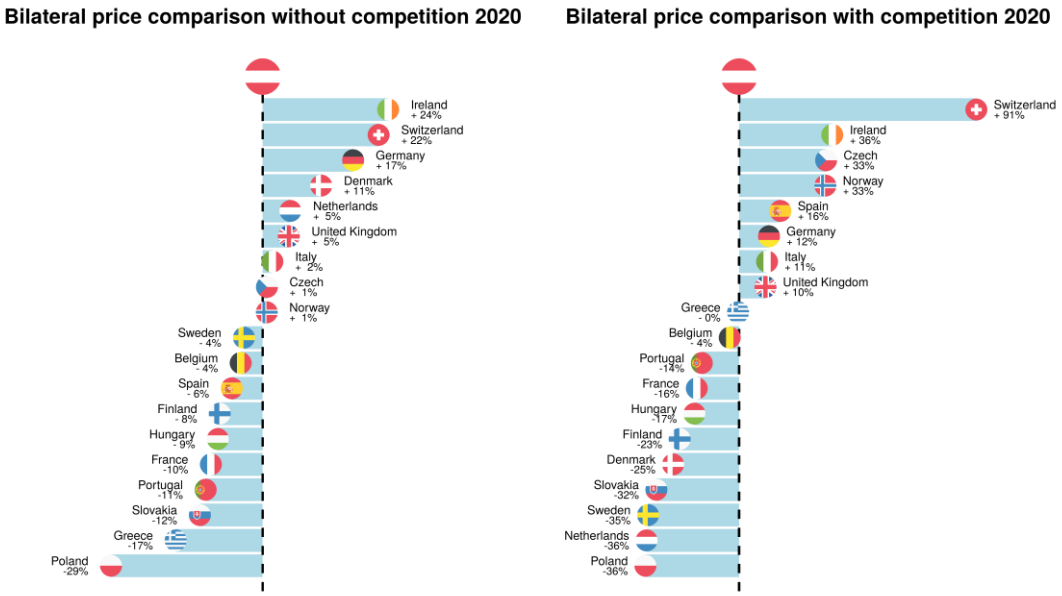
The second figure shows a bilateral price comparison for pharmaceuticals without competition where the country's prices during the first quarter of 2020 are compared with other countries' prices during the same period. The comparison is paired, which means that the pharmaceuticals with sales both in the country in question and in each individual comparison country are included in the comparison. The comparison is also weighted based on the volumes prescribed in the country in question and shows what the *country's pharmaceutical use, with the country's volumes, would have cost at other countries' prices*. Compare to Figure 8 in the main report.

The third figure shows a bilateral comparison for pharmaceuticals with competition. It is the same method used in the previous figure. Compare to Figure 14 in the main report.

The bottom figure shows the percentage deviation between prices in the country and the average prices in other countries from 2014 to 2020, for pharmaceuticals with and without competition. Prices are weighted based on the sales volumes of the country in question. Only pharmaceuticals available in at least 8 countries are included in the analysis. Compare to Figures 11 and 17 in the main report.

1 Austria


Pharmaceutical prices over its life cycle 2014-2020
Local prices
in relation to average prices
15%
0%
0
5
10
15
20
Years after first sale in Europe


Bilateral price comparison without competition 2020
Ireland
+ 24%
Switzerland
+ 22%
Germany
+ 17%
Denmark
+ 11%
Netherlands
+ 5%
United Kingdom
+ 5%
Italy
+ 2%
Czech
+ 1%
Norway
+ 1%
Sweden
- 4%
Belgium
- 4%
Spain
- 6%
Finland
- 8%
Hungary
- 9%
France
-10%
Portugal
-11%
Slovakia
-12%
Greece
-17%
Poland
-29%
Bilateral price comparison with competition 2020
Switzerland
+ 91%
Ireland
+ 36%
Czech
+ 33%
Norway
+ 33%
Spain
+ 16%
Germany
+ 12%
Italy
+ 11%
United Kingdom
+ 10%
Greece
- 0%
Belgium
- 4%
Portugal
-14%
France
-16%
Hungary
-17%
Finland
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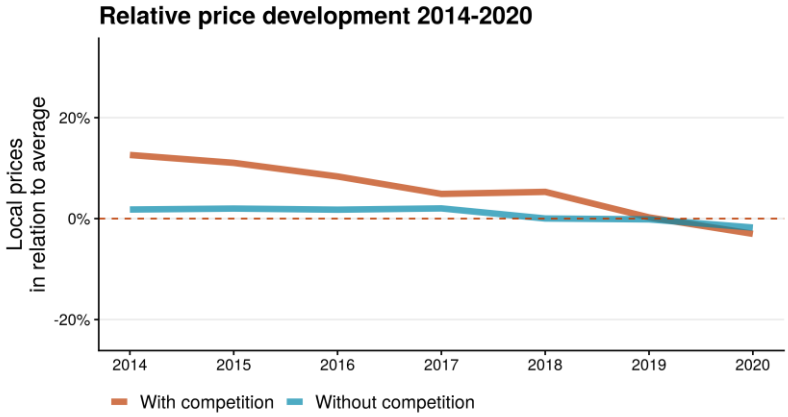
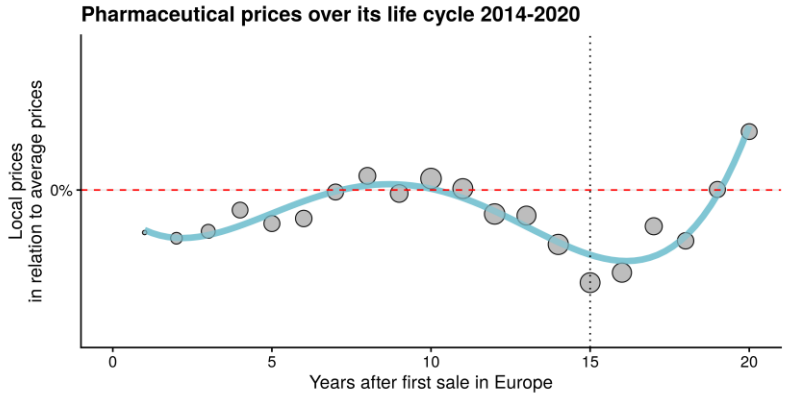
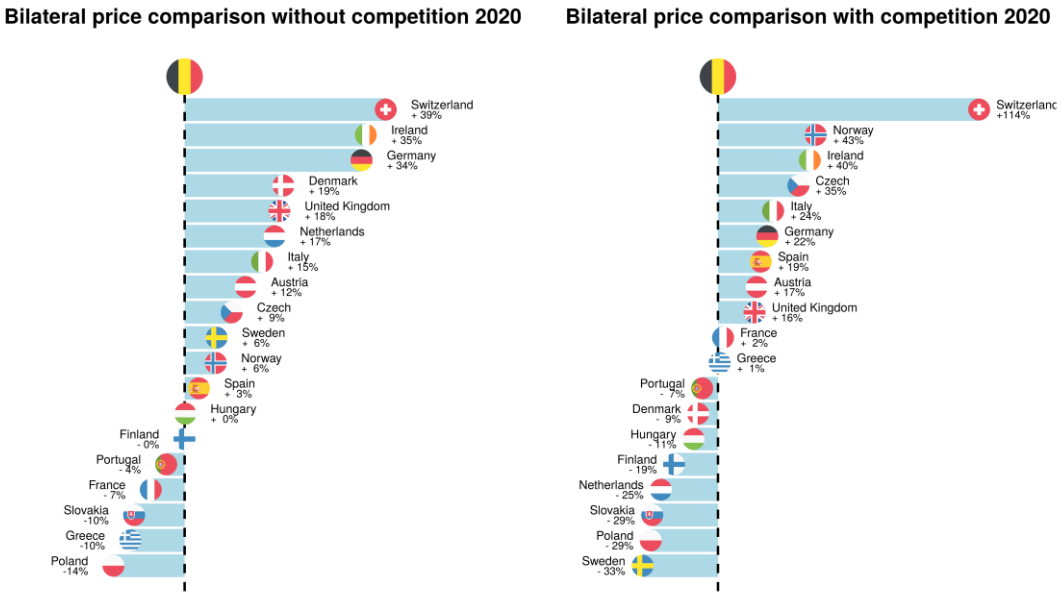
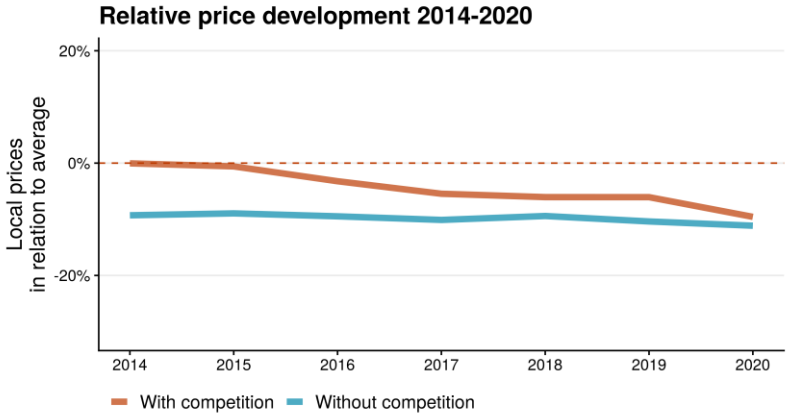
Denmark
-25%
Slovakia
-32%
Sweden
-35%
Netherlands
-36%
Poland
-36%


Relative price development 2014-2020
Local prices
in relation to average
20%
0%
-20%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

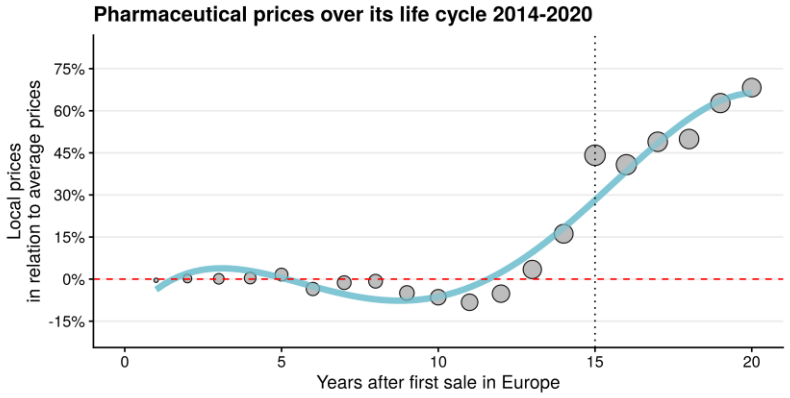
2 Belgium


Pharmaceutical prices over its life cycle 2014-2020
Local prices
in relation to average prices
0%
0
5
10
15
20
Years after first sale in Europe

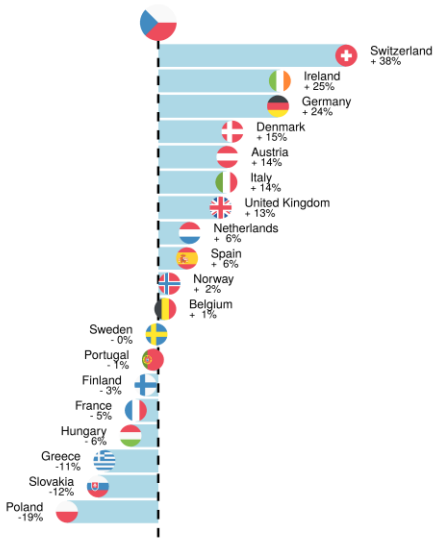

Bilateral price comparison without competition 2020
Switzerland + 39%
Ireland + 35%
Germany + 34%
Denmark + 19%
United Kingdom + 18%
Netherlands + 17%
Italy + 15%
Austria + 12%
Czech + 9%
Sweden + 6%
Norway + 6%
Spain + 3%
Hungary + 0%
Finland - 0%
Portugal - 4%
France - 7%
Slovakia -10%
Greece -10%
Poland -14%
Bilateral price comparison with competition 2020
Switzerland +114%
Norway + 43%
Ireland + 40%
Czech + 35%
Italy + 24%
Germany + 22%
Spain + 19%
Austria + 17%
United Kingdom + 16%
France + 2%
Greece + 1%
Portugal - 7%
Denmark - 9%
Hungary - 11%
Finland - 19%
Netherlands - 25%
Slovakia - 29%
Poland - 29%
Sweden - 33%


Relative price development 2014-2020
Local prices
in relation to average
20%
0%
-20%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

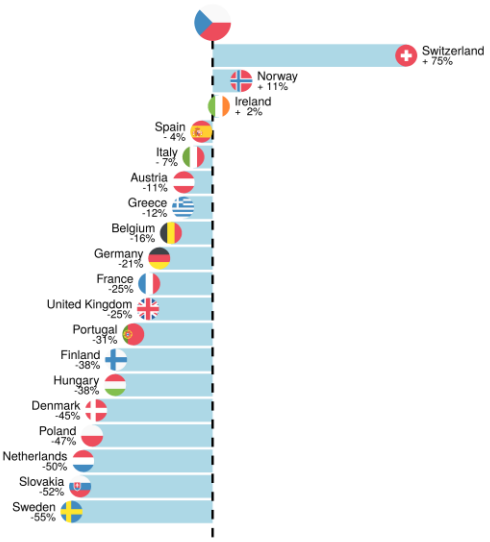
3 Czech Republic

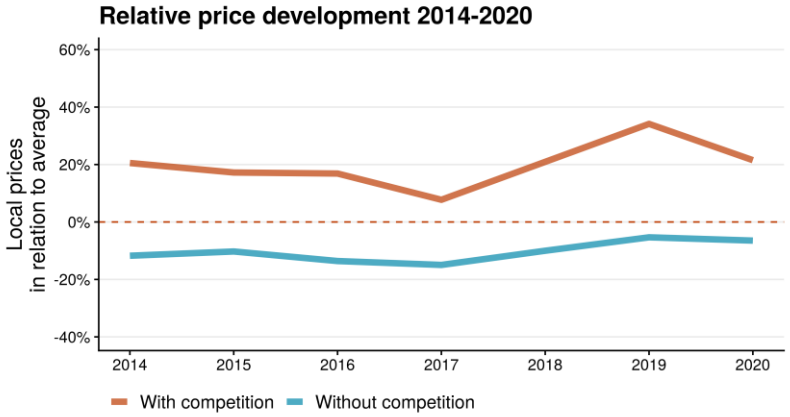


Bilateral price comparison without competition 2020

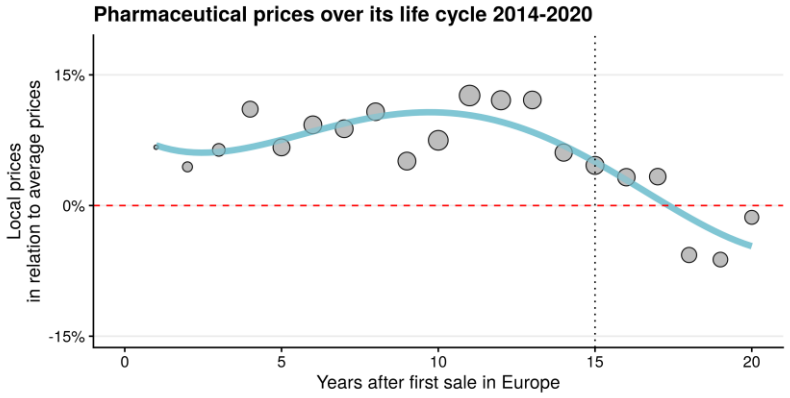


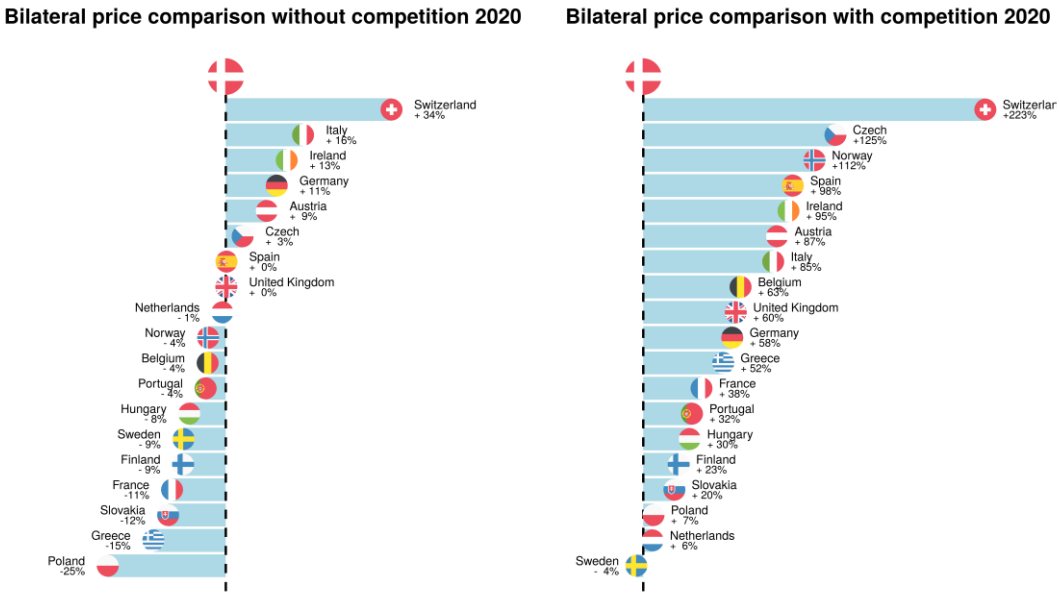
Bilateral price comparison with competition 2020

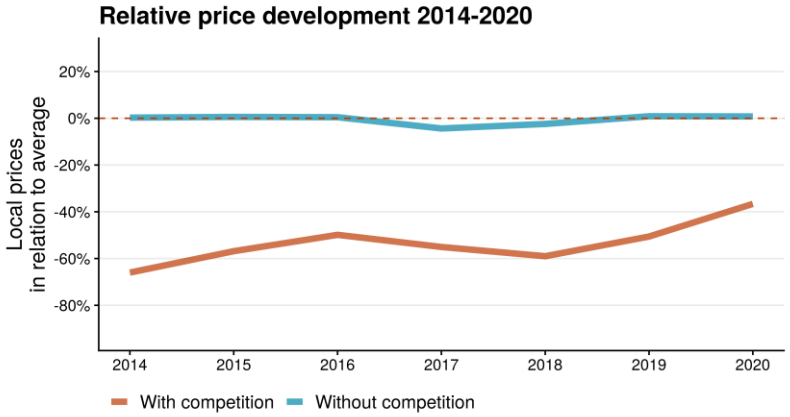




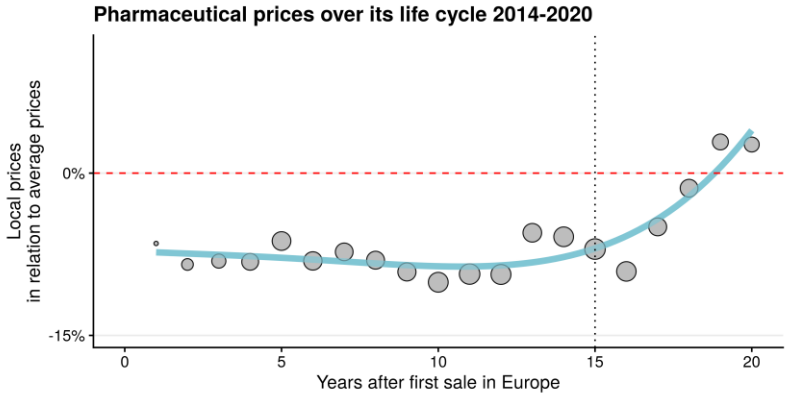
4 Denmark


Pharmaceutical prices over its life cycle 2014-2020
Local prices in relation to average prices
15%
0%
-15%
0
5
10
15
20
Years after first sale in Europe

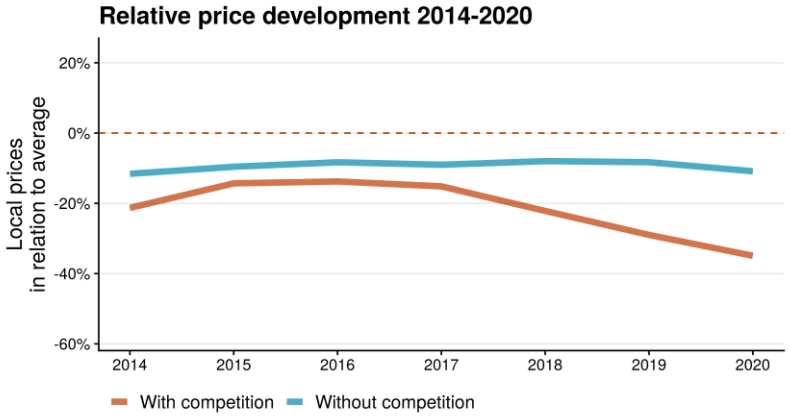

Bilateral price comparison without competition 2020
Switzerland + 34%
Italy + 16%
Ireland + 13%
Germany + 11%
Austria + 9%
Czech + 3%
Spain + 0%
United Kingdom + 0%
Netherlands - 1%
Norway - 4%
Belgium - 4%
Portugal - 8%
Hungary - 8%
Sweden - 9%
Finland - 9%
France -11%
Slovakia -12%
Greece -15%
Poland -25%
Bilateral price comparison with competition 2020
Switzerlar +223%
Czech +125%
Norway +112%
Spain + 98%
Ireland + 95%
Austria + 87%
Italy + 85%
Belgium + 63%
United Kingdom + 60%
Germany + 58%
Greece + 52%
France + 38%
Portugal + 32%
Hungary + 30%
Finland + 23%
Slovakia + 20%
Poland + 7%
Netherlands + 6%
Sweden - 4%


Relative price development 2014-2020
Local prices in relation to average
20%
0%
-20%
-40%
-60%
-80%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

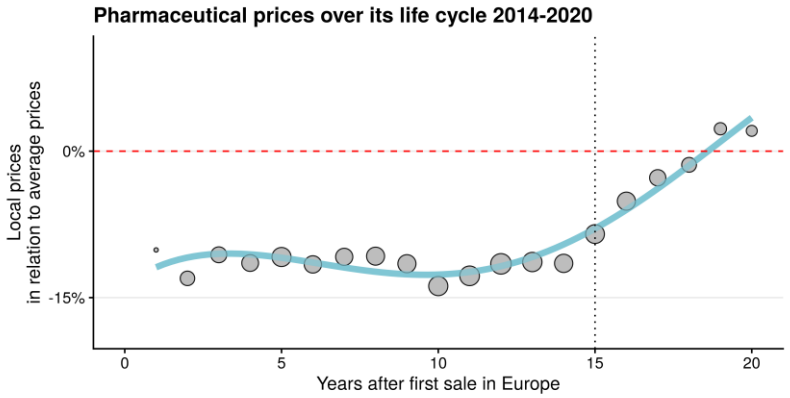
5 Finland

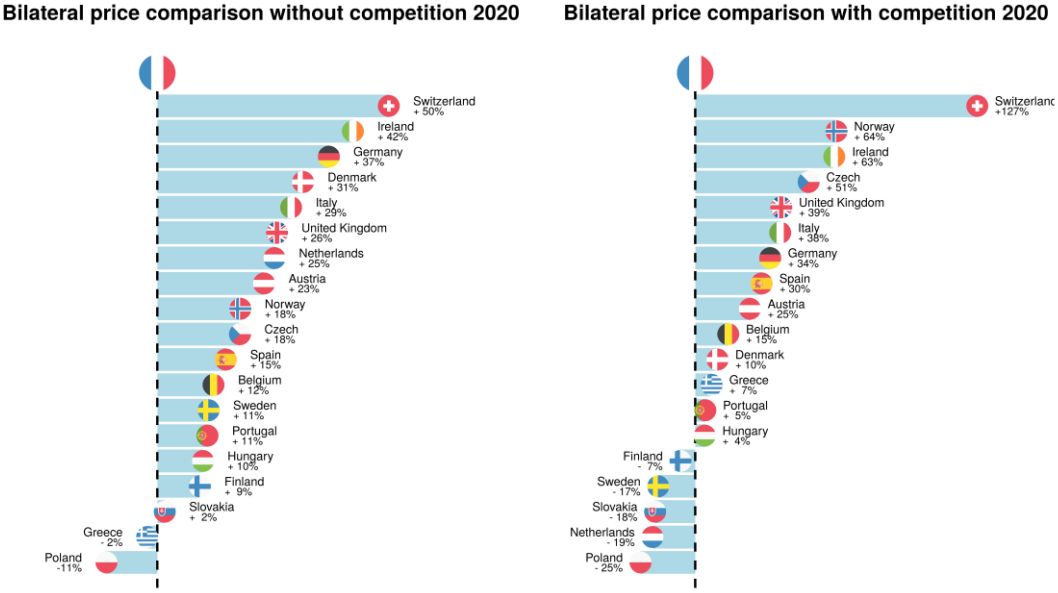

Pharmaceutical prices over its life cycle 2014-2020
Local prices
in relation to average prices
0%
-15%
0
5
10
15
20
Years after first sale in Europe

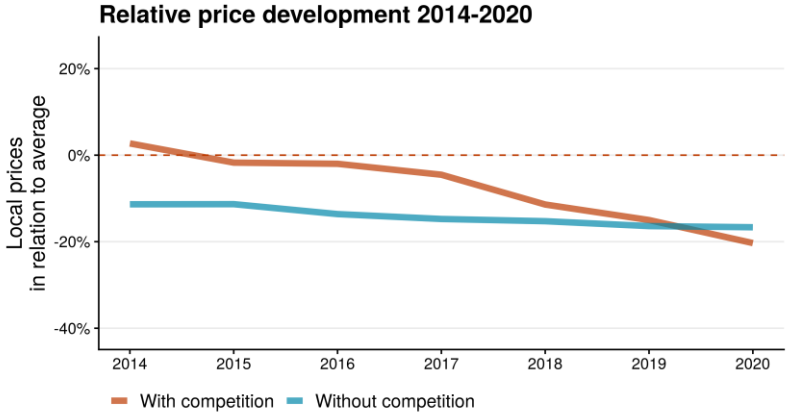

Bilateral price comparison without competition 2020
Switzerland + 41%
Germany + 34%
Ireland + 32%
Denmark + 30%
Italy + 26%
Netherlands + 18%
United Kingdom + 15%
Austria + 14%
Czech + 9%
Norway + 9%
Spain + 7%
Belgium + 6%
Portugal + 5%
Hungary + 3%
Sweden + 3%
France - 1%
Slovakia - 6%
Greece - 8%
Poland -19%
Bilateral price comparison with competition 2020
Switzerlan +209%
Norway +108%
Czech + 99%
Ireland + 97%
Spain + 85%
Italy + 81%
Austria + 70%
Greece + 65%
Belgium + 58%
United Kingdom + 57%
Germany + 56%
France + 40%
Portugal + 38%
Hungary + 24%
Denmark + 19%
Poland + 1%
Slovakia - 0%
Netherlands - 4%
Sweden - 9%


Relative price development 2014-2020
Local prices
in relation to average
20%
0%
-20%
-40%
-60%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

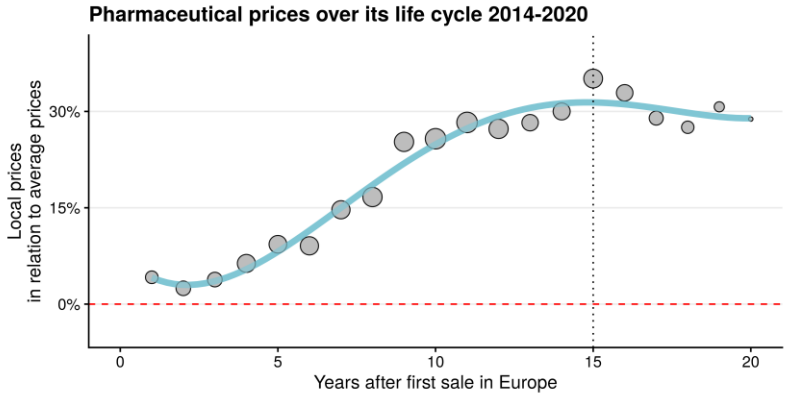
6 France

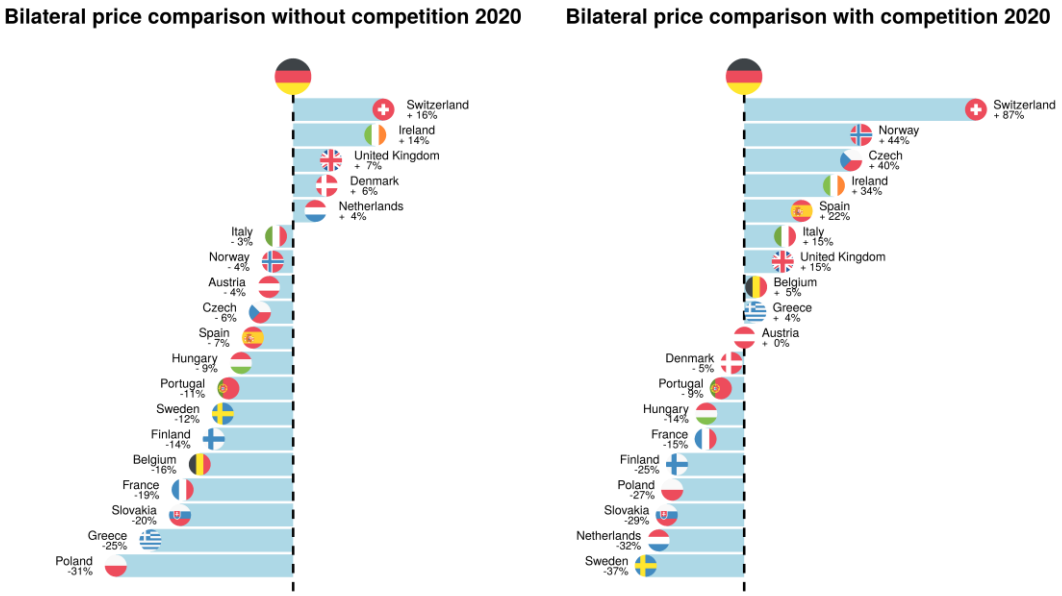

Pharmaceutical prices over its life cycle 2014-2020
Local prices in relation to average prices
0%
-15%
0
5
10
15
20
Years after first sale in Europe

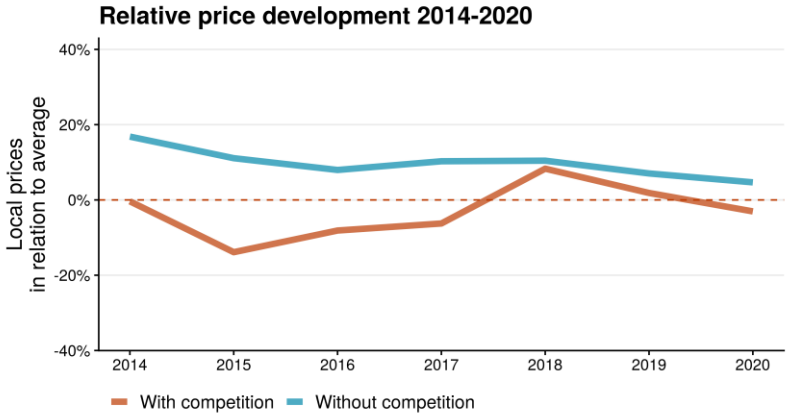

Bilateral price comparison without competition 2020
Switzerland + 50%
Ireland + 42%
Germany + 37%
Denmark + 31%
Italy + 29%
United Kingdom + 26%
Netherlands + 25%
Austria + 23%
Norway + 18%
Czech + 18%
Spain + 15%
Belgium + 12%
Sweden + 11%
Portugal + 11%
Hungary + 10%
Finland + 9%
Slovakia + 2%
Greece - 2%
Poland -11%
Bilateral price comparison with competition 2020
Switzerland +127%
Norway + 64%
Ireland + 63%
Czech + 51%
United Kingdom + 39%
Italy + 38%
Germany + 34%
Spain + 30%
Austria + 25%
Belgium + 15%
Denmark + 10%
Greece + 7%
Portugal + 5%
Hungary + 4%
Finland - 7%
Sweden - 17%
Slovakia - 18%
Netherlands - 19%
Poland - 25%


Relative price development 2014-2020
Local prices in relation to average
20%
0%
-20%
-40%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

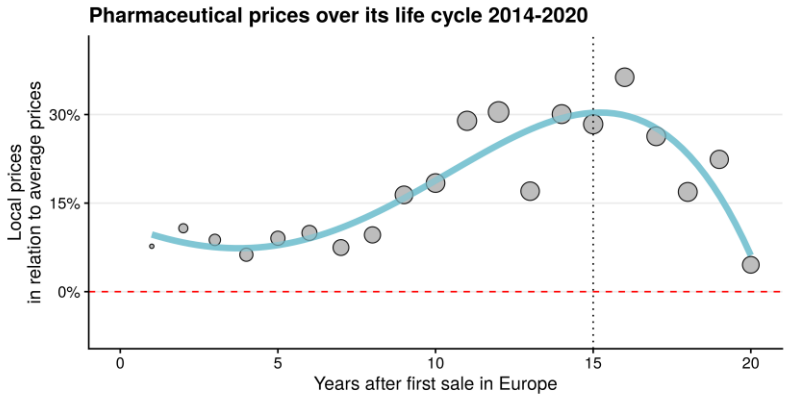
7 Germany

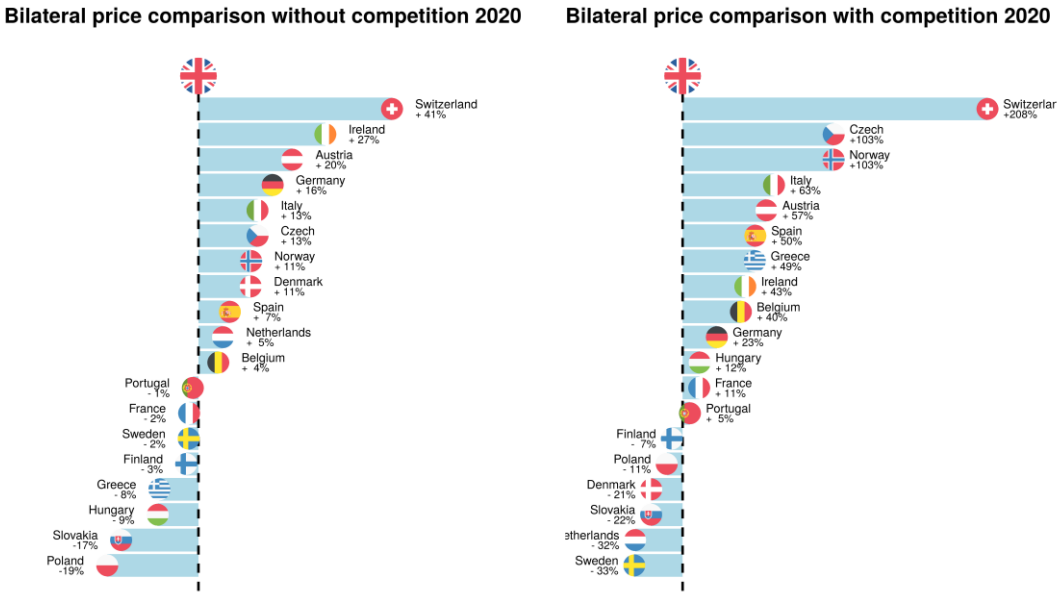

Pharmaceutical prices over its life cycle 2014-2020
Local prices
in relation to average prices
30%
15%
0%
0
5
10
15
20
Years after first sale in Europe

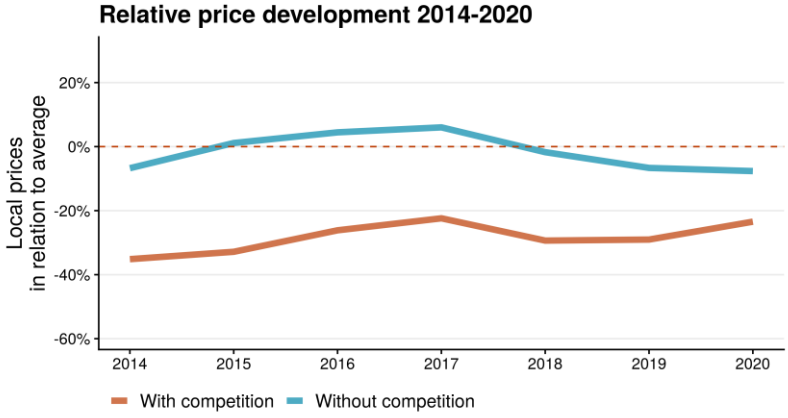

Bilateral price comparison without competition 2020
Switzerland + 16%
Ireland + 14%
United Kingdom + 7%
Denmark + 6%
Netherlands + 4%
Italy - 3%
Norway - 4%
Austria - 4%
Czech - 6%
Spain - 7%
Hungary - 9%
Portugal -11%
Sweden -12%
Finland -14%
Belgium -16%
France -19%
Slovakia -20%
Greece -25%
Poland -31%
Bilateral price comparison with competition 2020
Switzerland + 87%
Norway + 44%
Czech + 40%
Ireland + 34%
Spain + 22%
Italy + 15%
United Kingdom + 15%
Belgium + 5%
Greece + 4%
Austria + 0%
Denmark - 5%
Portugal - 8%
Hungary -14%
France -15%
Finland -25%
Poland -27%
Slovakia -29%
Netherlands -32%
Sweden -37%


Relative price development 2014-2020
Local prices
in relation to average
40%
20%
0%
-20%
-40%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

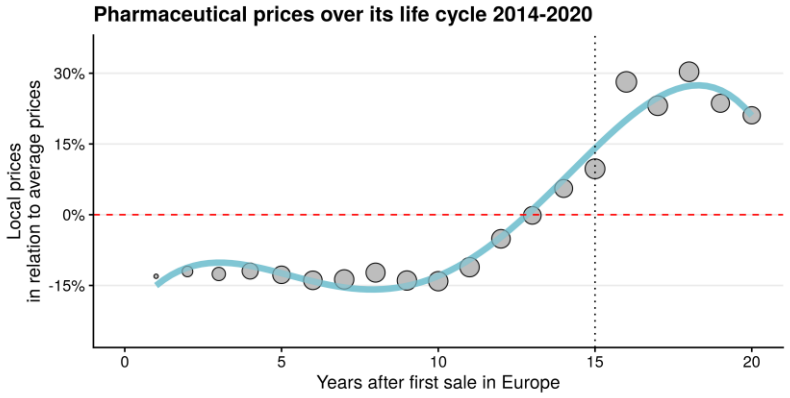
8 United Kingdom



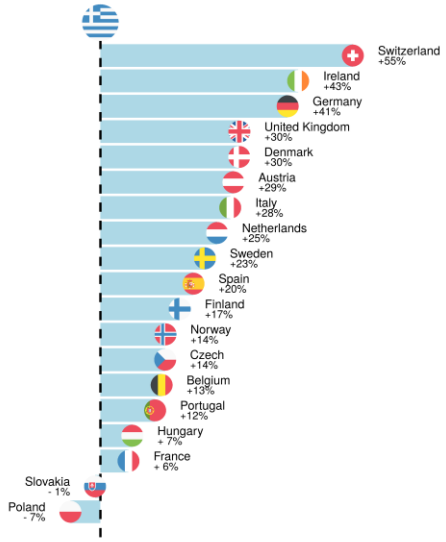




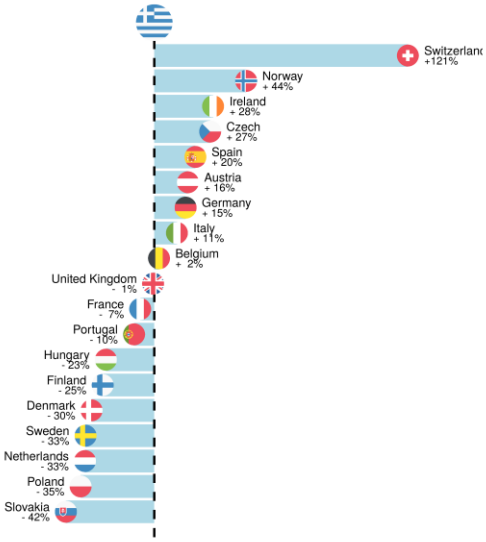
9 Greece

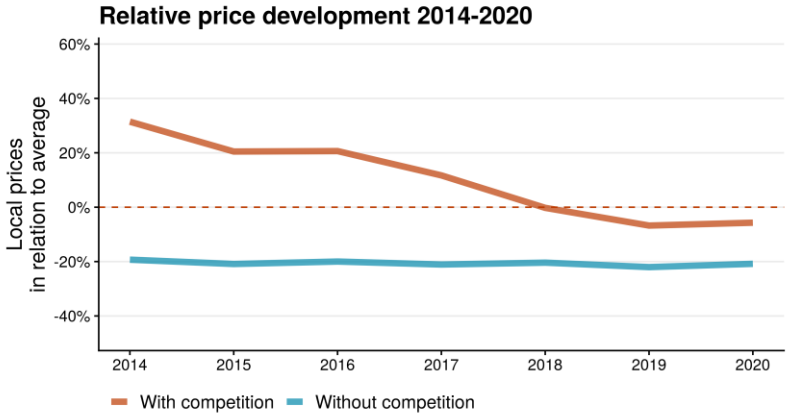


Bilateral price comparison without competition 2020

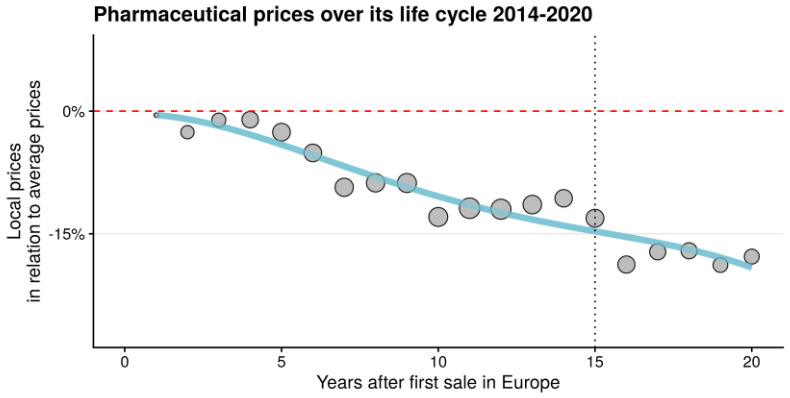


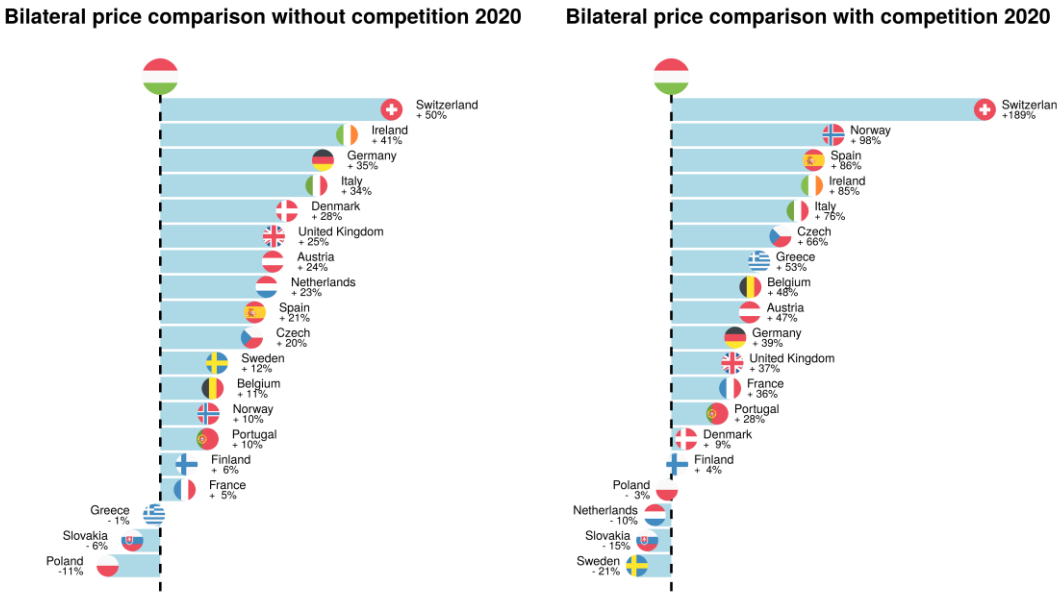
Bilateral price comparison with competition 2020

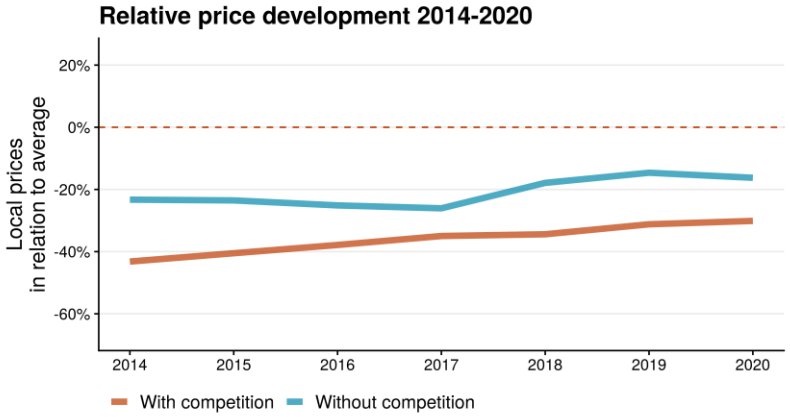




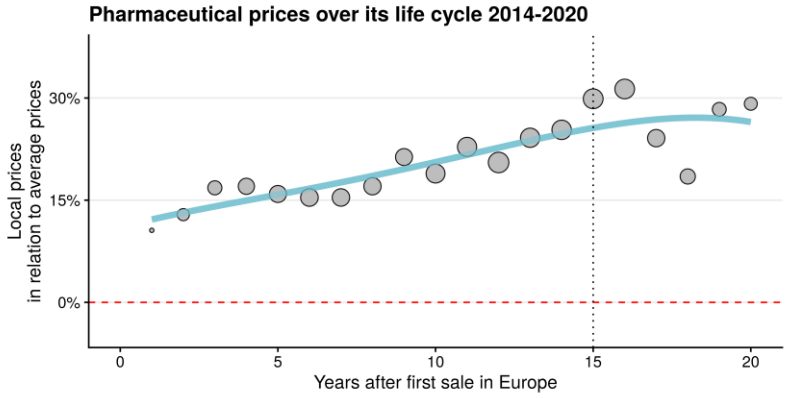
10 Hungary

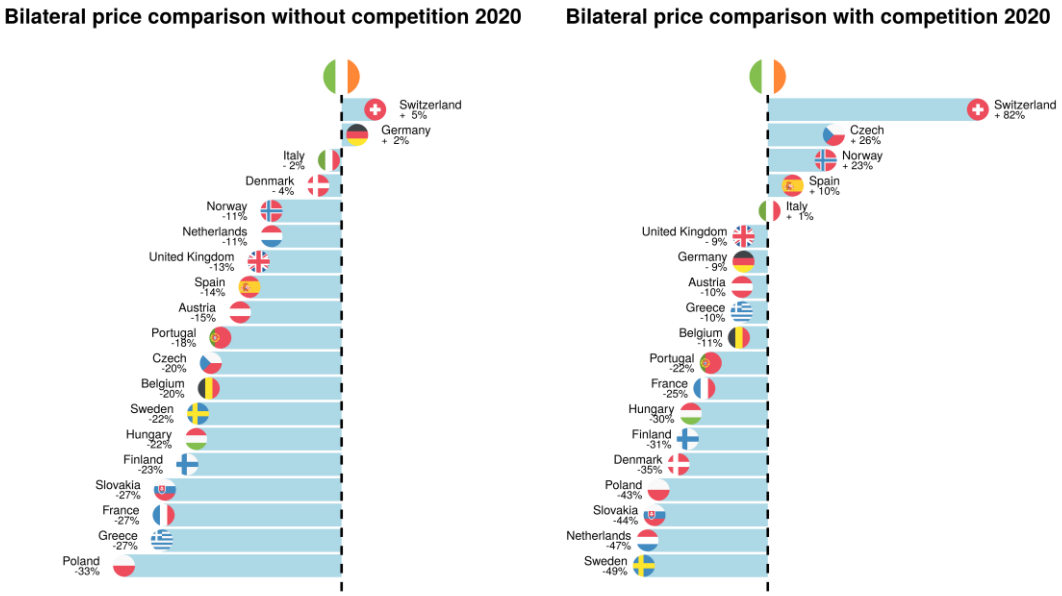

Pharmaceutical prices over its life cycle 2014-2020
Local prices
in relation to average prices
0%
-15%
0
5
10
15
20
Years after first sale in Europe

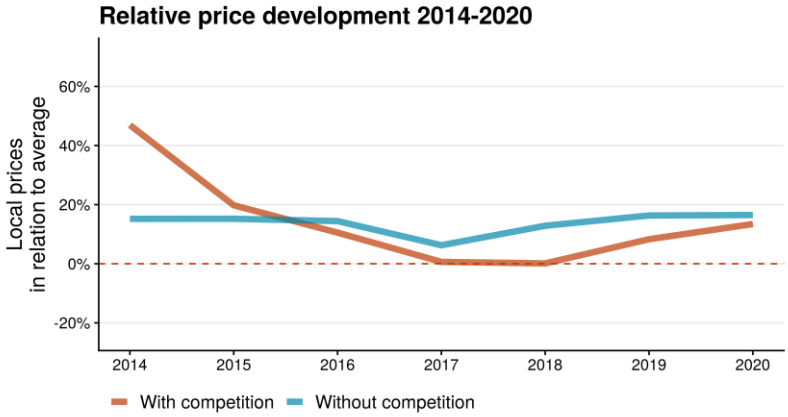

Bilateral price comparison without competition 2020
Switzerland + 50%
Ireland + 41%
Germany + 35%
Italy + 34%
Denmark + 28%
United Kingdom + 25%
Austria + 24%
Netherlands + 23%
Spain + 21%
Czech + 20%
Sweden + 12%
Belgium + 11%
Norway + 10%
Portugal + 10%
Finland + 6%
France + 5%
Greece - 1%
Slovakia - 6%
Poland -11%
Bilateral price comparison with competition 2020
Switzerlan +189%
Norway + 98%
Spain + 86%
Ireland + 85%
Italy + 76%
Czech + 66%
Greece + 53%
Belgium + 48%
Austria + 47%
Germany + 39%
United Kingdom + 37%
France + 36%
Portugal + 28%
Denmark + 9%
Finland + 4%
Poland - 3%
Netherlands - 10%
Slovakia - 15%
Sweden - 21%


Relative price development 2014-2020
Local prices
in relation to average
20%
0%
-20%
-40%
-60%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

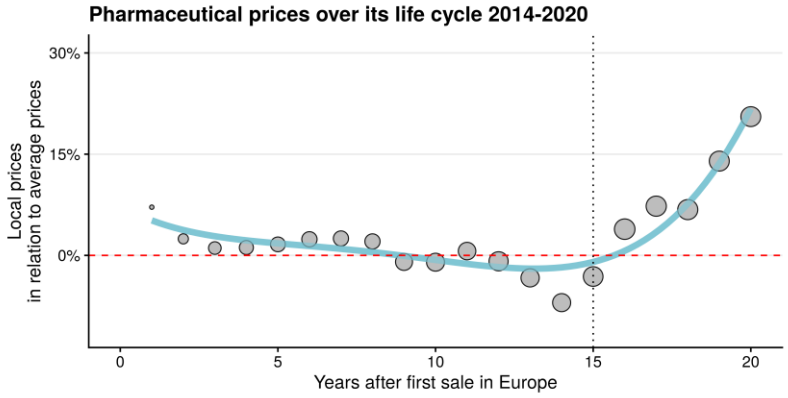
11 Ireland


Pharmaceutical prices over its life cycle 2014-2020
Local prices in relation to average prices
30%
15%
0%
0
5
10
15
20
Years after first sale in Europe

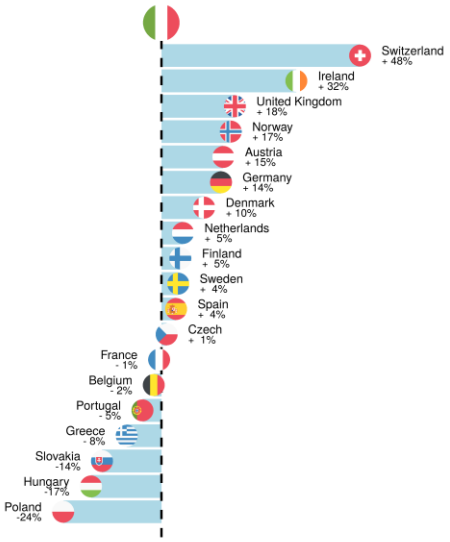

Bilateral price comparison without competition 2020
Switzerland + 5%
Germany + 2%
Italy - 2%
Denmark - 4%
Norway -11%
Netherlands -11%
United Kingdom -13%
Spain -14%
Austria -15%
Portugal -18%
Czech -20%
Belgium -20%
Sweden -22%
Hungary -22%
Finland -23%
Slovakia -27%
France -27%
Greece -27%
Poland -33%
Bilateral price comparison with competition 2020
Switzerland + 82%
Czech + 26%
Norway + 23%
Spain + 10%
Italy + 1%
United Kingdom - 9%
Germany - 9%
Austria -10%
Greece -10%
Belgium -11%
Portugal -22%
France -25%
Hungary -30%
Finland -31%
Denmark -35%
Poland -43%
Slovakia -44%
Netherlands -47%
Sweden -49%


Relative price development 2014-2020
Local prices in relation to average
60%
40%
20%
0%
-20%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

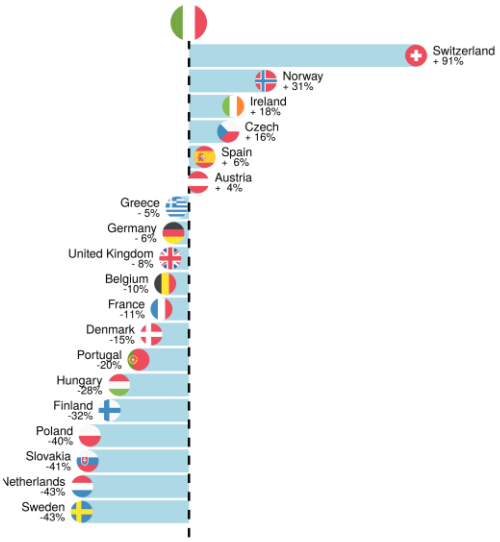
12 Italy

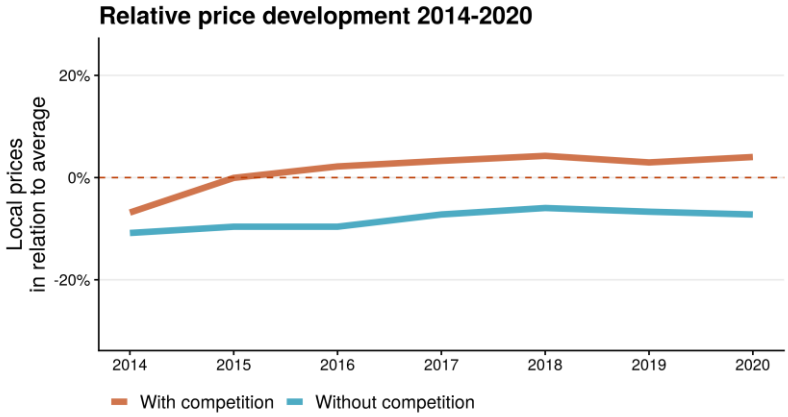


Bilateral price comparison without competition 2020

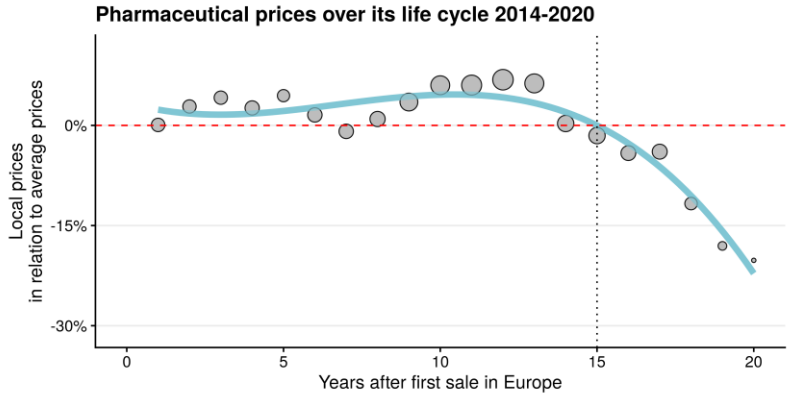


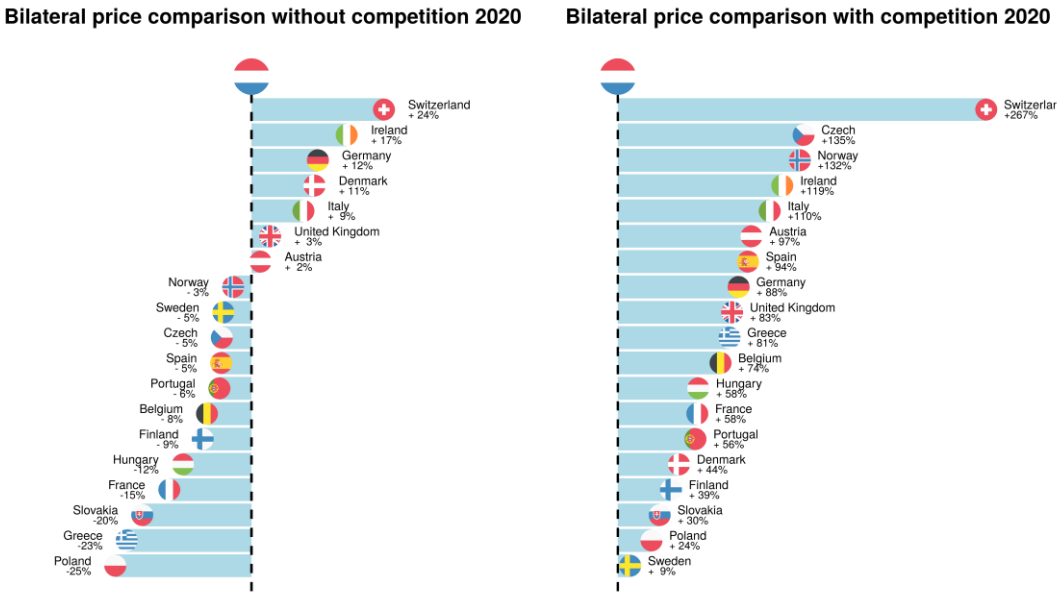
Bilateral price comparison with competition 2020

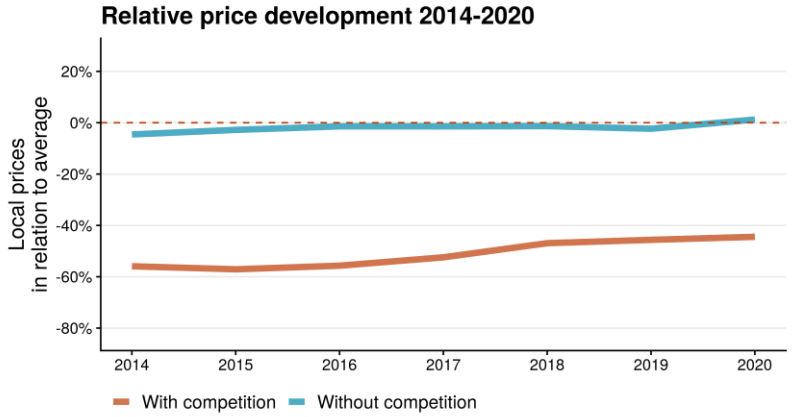




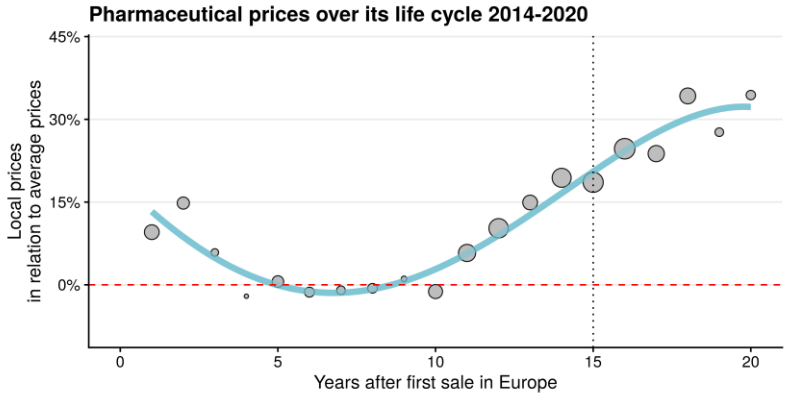
13 The Netherlands



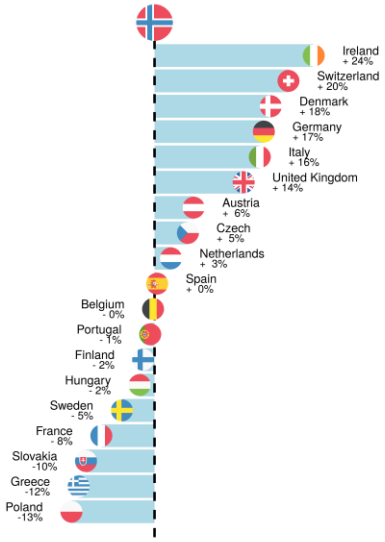




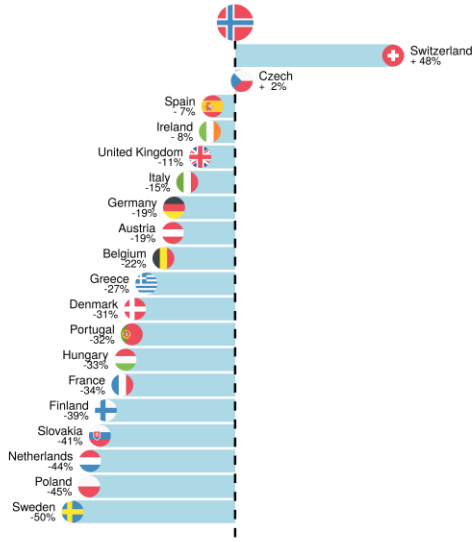
14 Norway



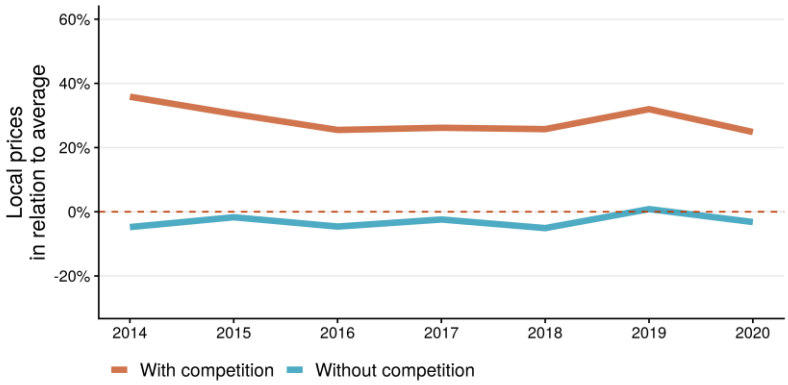
Bilateral price comparison without competition 2020



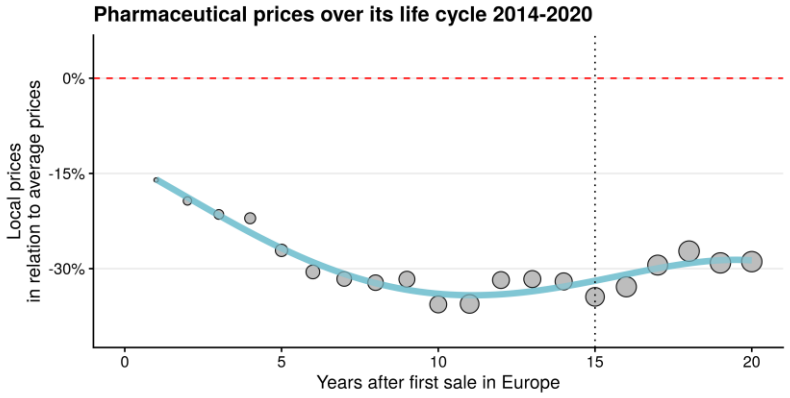
Bilateral price comparison with competition 2020



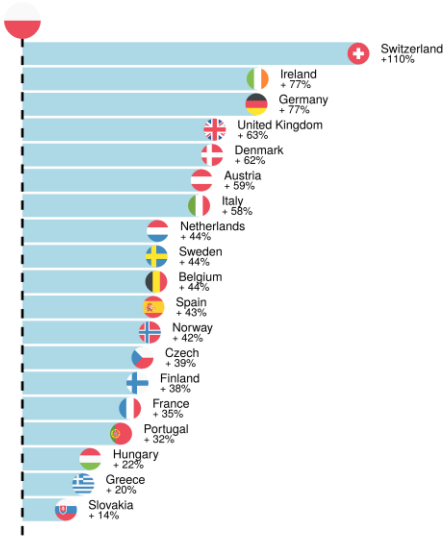
Relative price development 2014-2020



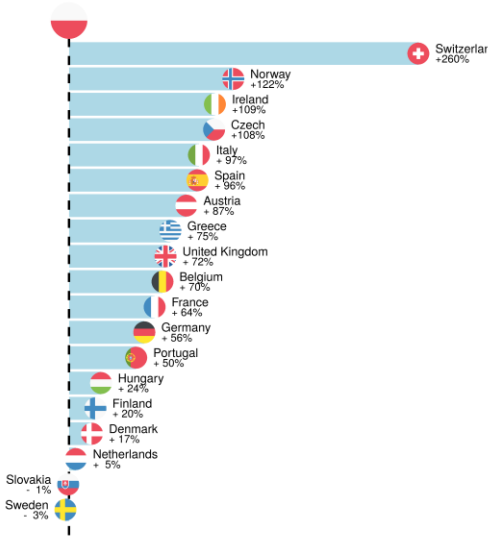
15 Poland

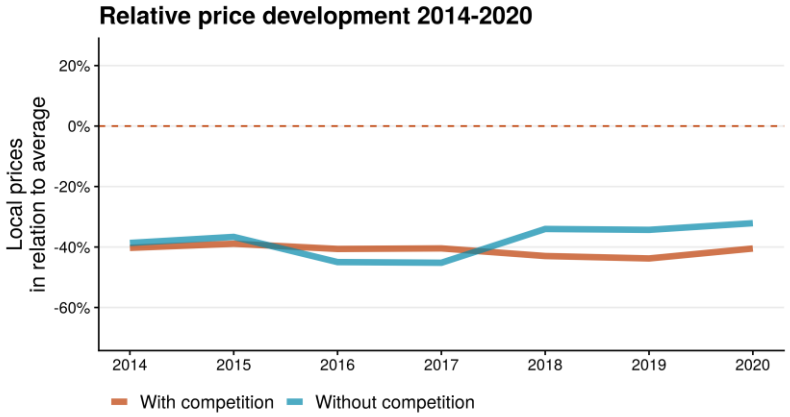


Bilateral price comparison without competition 2020

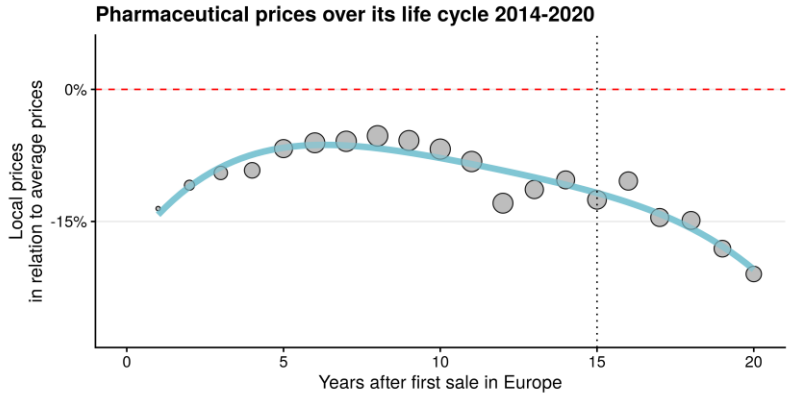


Bilateral price comparison with competition 2020

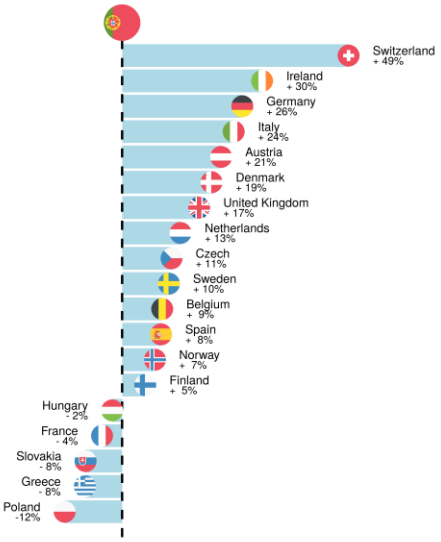




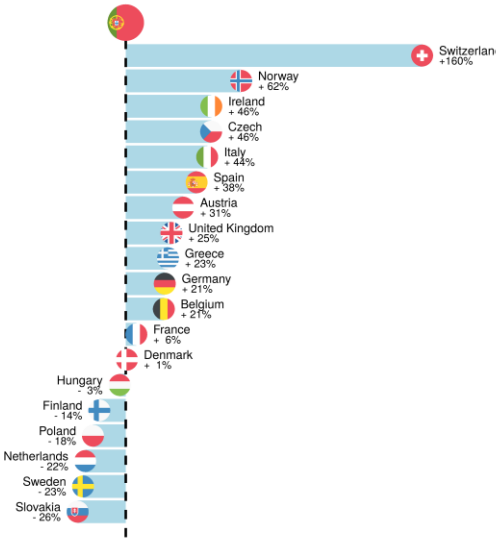
16 Portugal

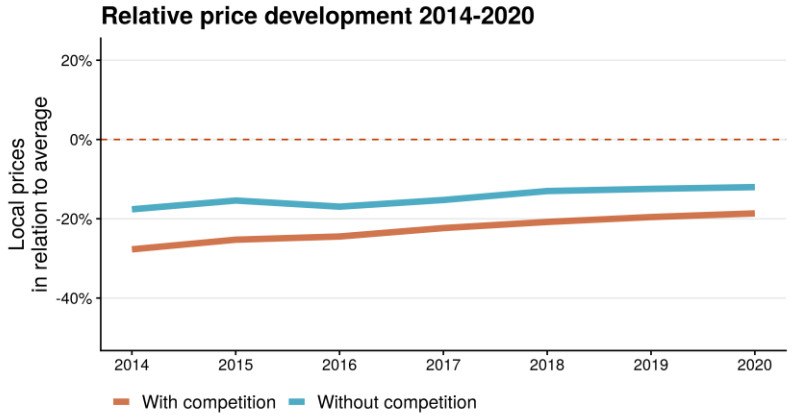


Bilateral price comparison without competition 2020

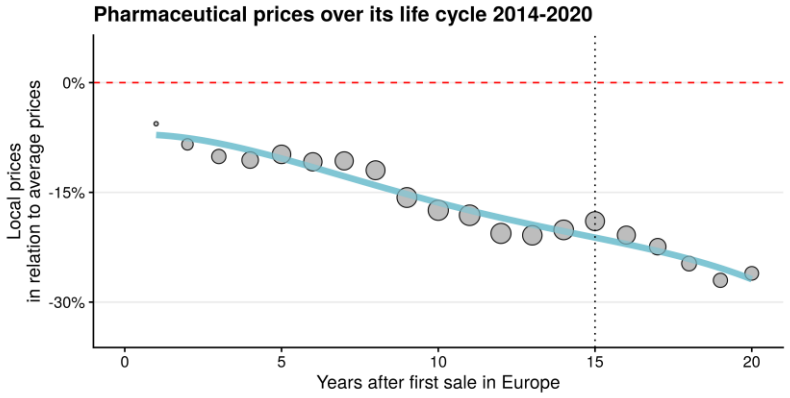


Bilateral price comparison with competition 2020

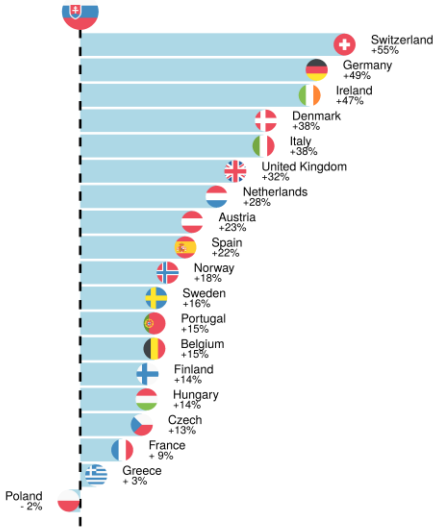




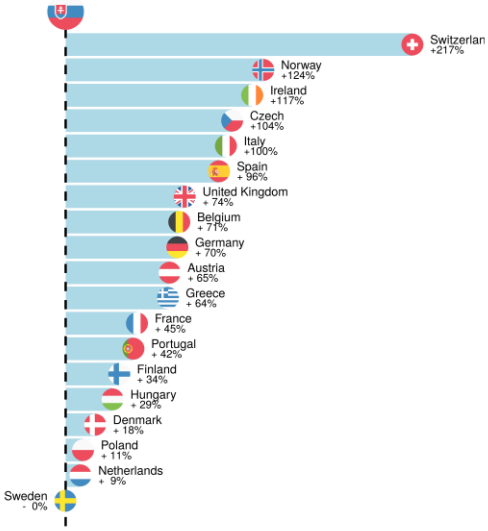
17 Slovakia

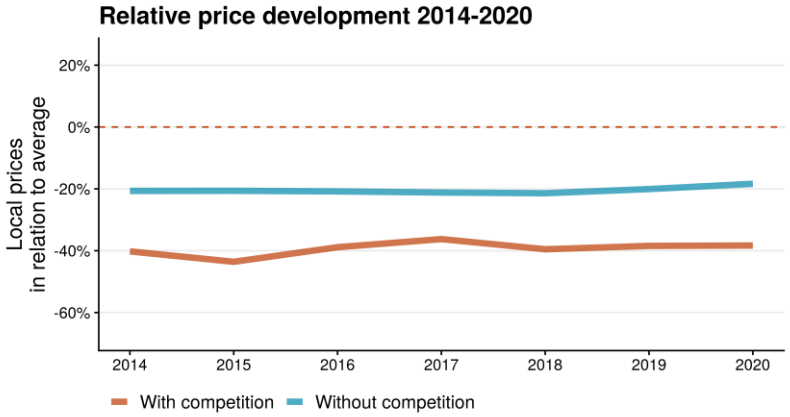


Bilateral price comparison without competition 2020

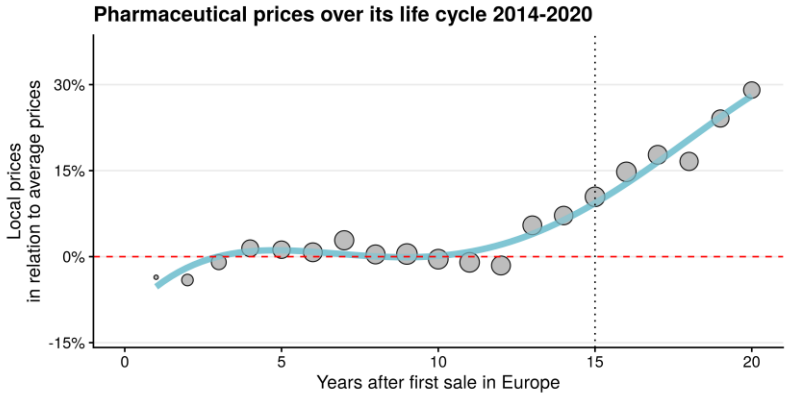


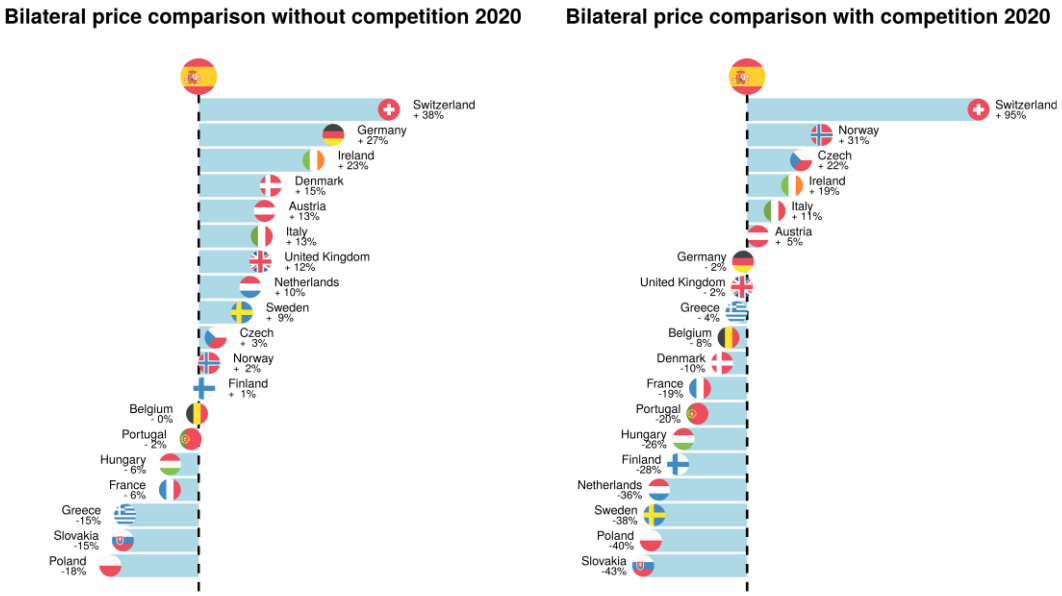
Bilateral price comparison with competition 2020

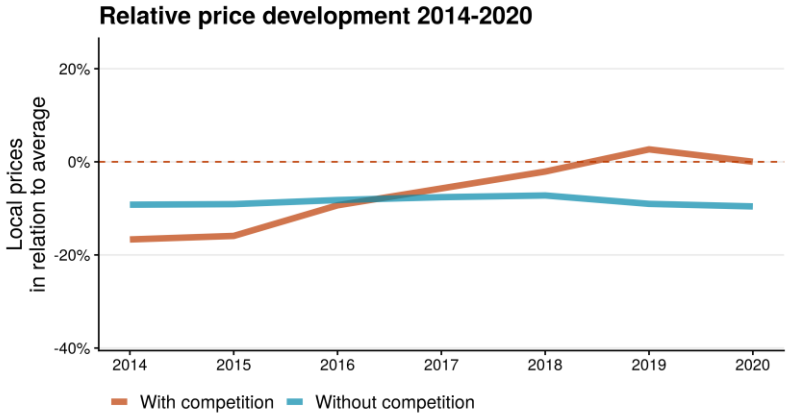




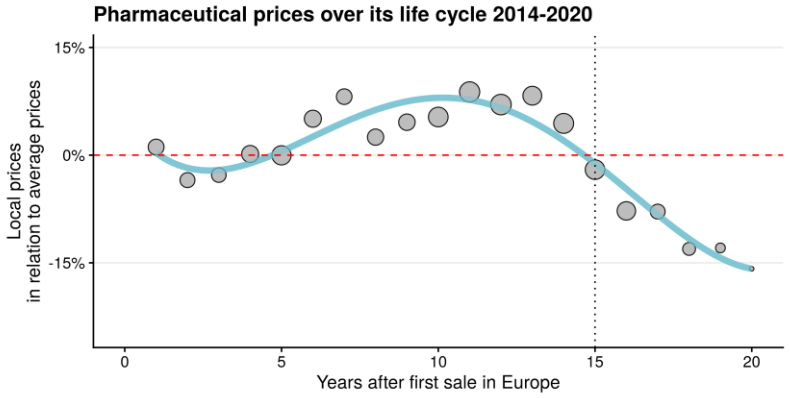
18 Spain

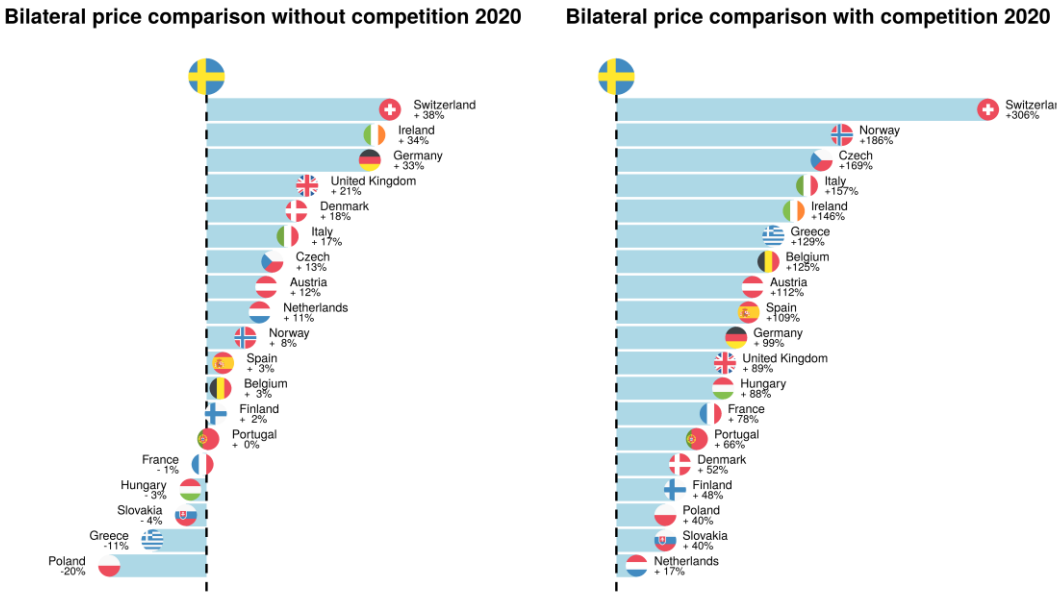

Pharmaceutical prices over its life cycle 2014-2020
Local prices
in relation to average prices
30%
15%
0%
-15%
0
5
10
15
20
Years after first sale in Europe

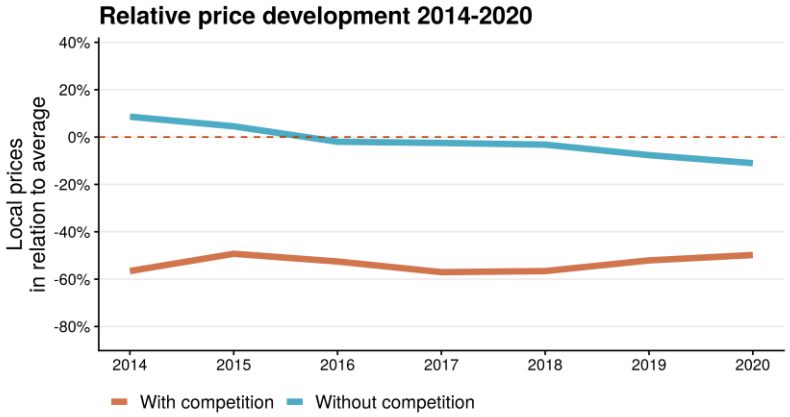

Bilateral price comparison without competition 2020
Switzerland
+ 38%
Germany
+ 27%
Ireland
+ 23%
Denmark
+ 15%
Austria
+ 13%
Italy
+ 13%
United Kingdom
+ 12%
Netherlands
+ 10%
Sweden
+ 9%
Czech
+ 3%
Norway
+ 2%
Finland
+ 1%
Belgium
- 0%
Portugal
- 2%
Hungary
- 6%
France
- 6%
Greece
-15%
Slovakia
-15%
Poland
-18%
Bilateral price comparison with competition 2020
Switzerland
+ 95%
Norway
+ 31%
Czech
+ 22%
Ireland
+ 19%
Italy
+ 11%
Austria
+ 5%
Germany
- 2%
United Kingdom
- 2%
Greece
- 4%
Belgium
- 8%
Denmark
-10%
France
-19%
Portugal
-20%
Hungary
-26%
Finland
-28%
Netherlands
-36%
Sweden
-38%
Poland
-40%
Slovakia
-43%


Relative price development 2014-2020
Local prices
in relation to average
20%
0%
-20%
-40%
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

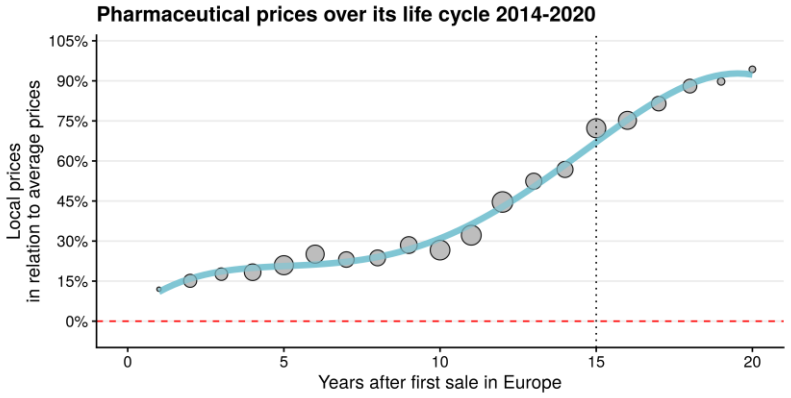
19 Sweden


Pharmaceutical prices over its life cycle 2014-2020
15%
0%
-15%
Local prices
in relation to average prices
0
5
10
15
20
Years after first sale in Europe

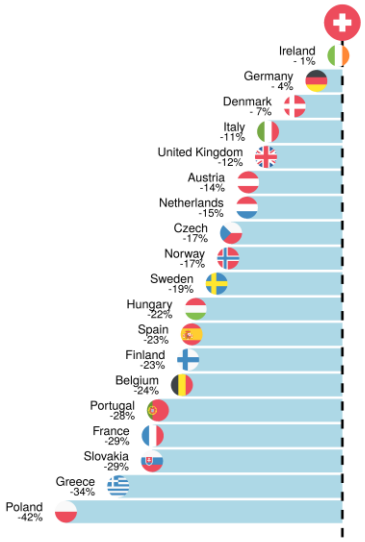

Bilateral price comparison without competition 2020
Switzerland + 38%
Ireland + 34%
Germany + 33%
United Kingdom + 21%
Denmark + 18%
Italy + 17%
Czech + 13%
Austria + 12%
Netherlands + 11%
Norway + 8%
Spain + 3%
Belgium + 3%
Finland + 2%
Portugal + 0%
France - 1%
Hungary - 3%
Slovakia - 4%
Greece -11%
Poland -20%
Bilateral price comparison with competition 2020
Switzerlar +306%
Norway +186%
Czech +169%
Italy +157%
Ireland +146%
Greece +129%
Belgium +125%
Austria +112%
Spain +109%
Germany + 99%
United Kingdom + 89%
Hungary + 88%
France + 78%
Portugal + 66%
Denmark + 52%
Finland + 48%
Poland + 40%
Slovakia + 40%
Netherlands + 17%


Relative price development 2014-2020
40%
20%
0%
-20%
-40%
-60%
-80%
Local prices
in relation to average
2014
2015
2016
2017
2018
2019
2020
With competition
Without competition

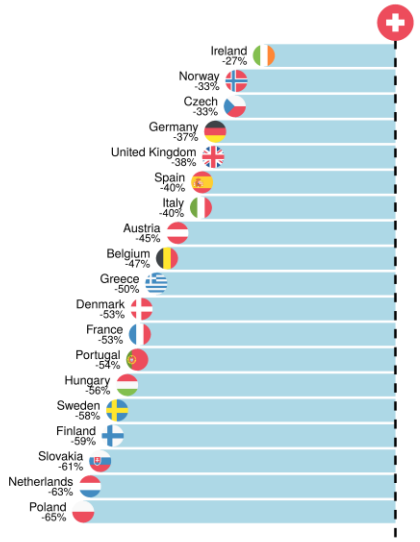
20 Switzerland

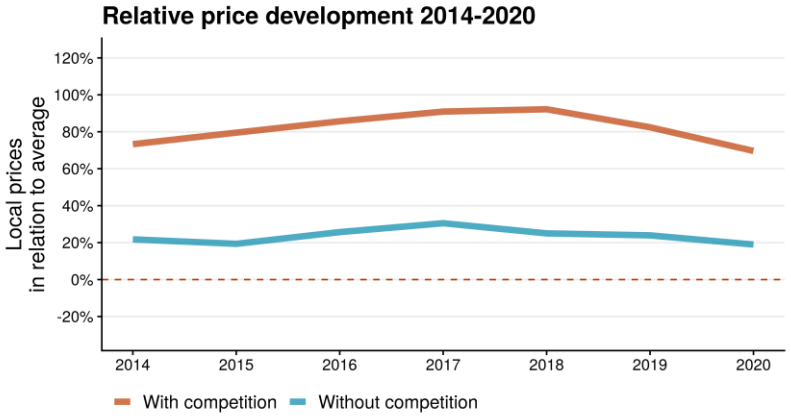


Bilateral price comparison without competition 2020



Bilateral price comparison with competition 2020





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