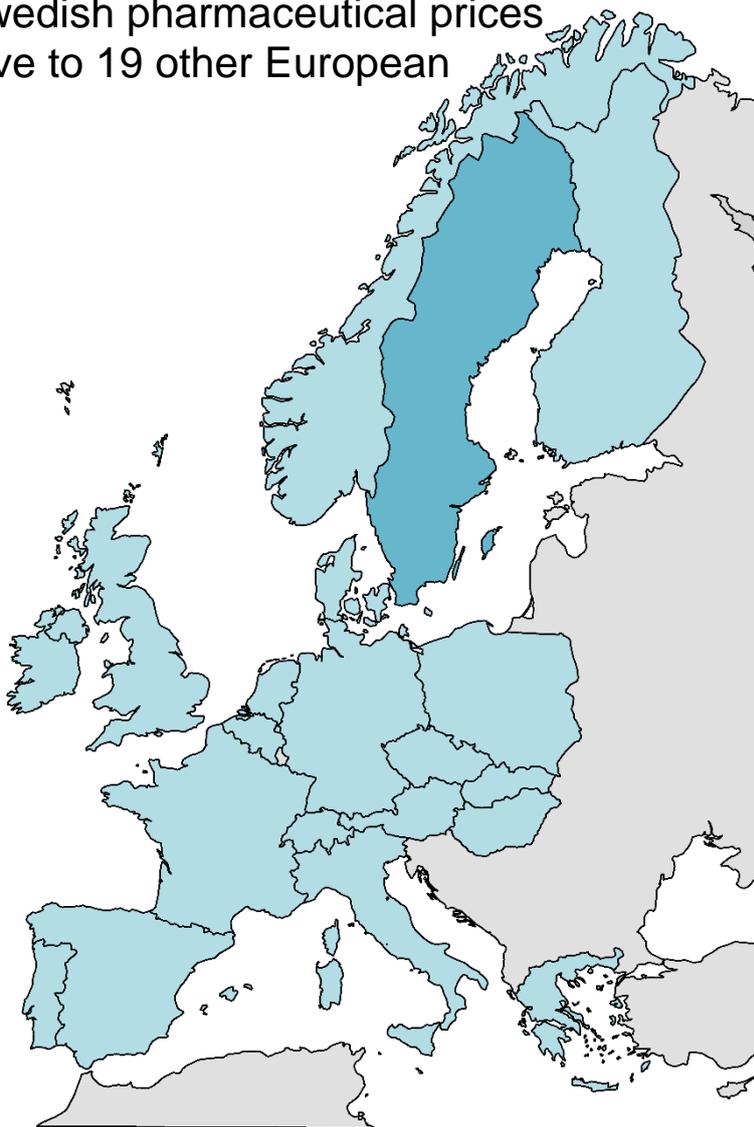


# International price comparison 2018

– an analysis of Swedish pharmaceutical prices  
and volumes relative to 19 other European  
countries



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Dental and Pharmaceutical Benefits Agency, December, 2018

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# Preface

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

In this report, TLV presents the results of the analysis of price and volume data for the first quarter of 2014, 2015, 2016, 2017 and 2018 in Sweden in comparison with 19 other European countries. The segments analysed are pharmaceuticals not exposed to competition and pharmaceuticals exposed to competition, with the latter including all pharmaceuticals available as substitutable medicines in the Swedish generic substitution system (product-of-the-month) as per March.

The report should be viewed as a basis for further analysis of the dynamics of Swedish prices and price changes compared to that seen internationally.

Sofia Wallström  
Director-General



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## Summary

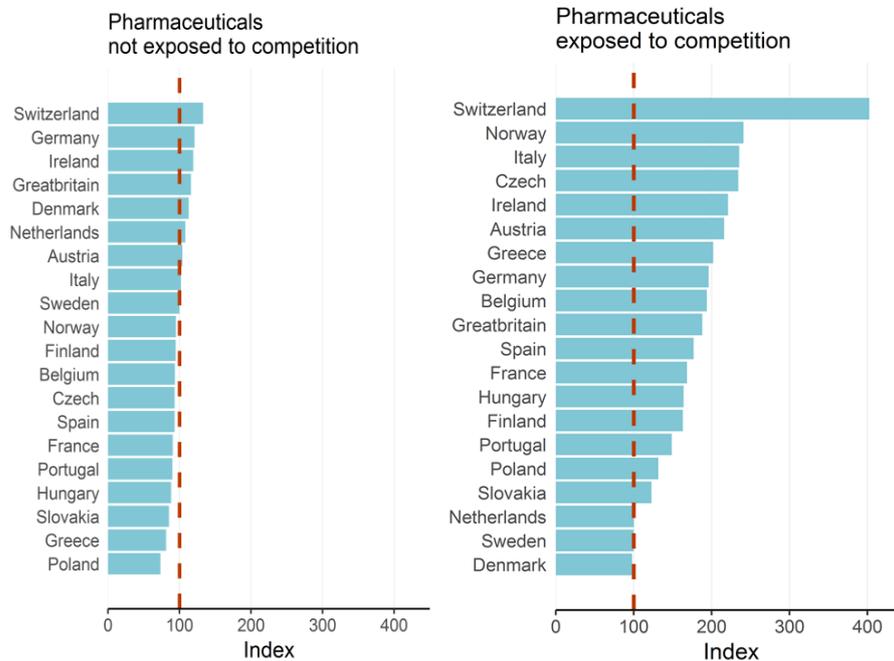
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This report is part of TLV's mandate to monitor developments in the Swedish pharmaceutical market from an international perspective. The report is the fifth report of its kind. The analysis is based on prescription pharmaceuticals in outpatient care.

TLV has used price and sales statistics from IQVIA (formerly IMS Health). The prices refer to prices that applied during the first quarter of each year in each country. The volumes refer to a rolling 12 months in Sweden up to and including the first quarter of each year between 2014 and 2018. Prices in Sweden are compared with prices in 19 other European countries. The report is based on national prices at pharmacy purchasing price (AIP). For the comparison, a three-year rolling average is applied to the exchange rate for each quarter, which means the results are less sensitive to currency fluctuations. The pharmaceuticals have been divided into two segments based on the conditions for competition in Sweden. Pharmaceuticals that are not substitutable are included in the segment for pharmaceuticals not exposed to competition, while products that are substitutable and included in the generic substitution system (product-of-the-month) for the period are included in the segment for pharmaceuticals that are exposed to competition.

The figures below show the bilateral indices for 2018, divided between pharmaceuticals not exposed to competition and pharmaceuticals exposed to competition. The index calculation is based on the price of pharmaceuticals in Sweden, which means that Sweden's index value is 100.

Figure 1: Bilateral price index by segment, Sweden = 100, prices 2018 Q1, volumes continuously for a period of 12 months up to and including March 2018, 3-year average exchange rate



Source: IQVIA and TLV analysis.

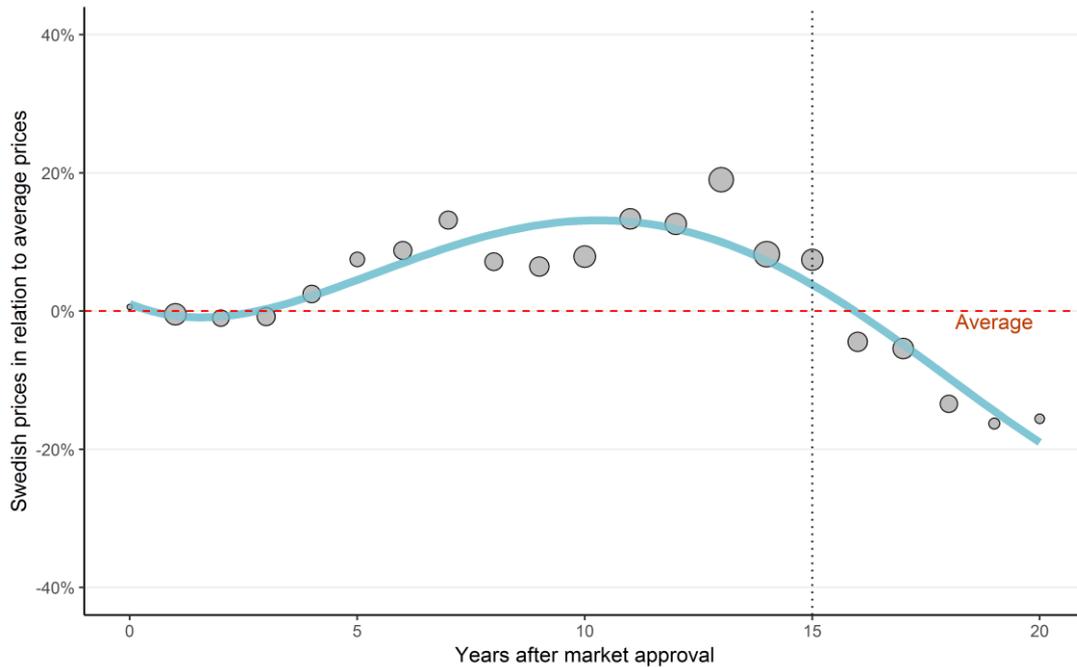
The Swedish prices are slightly above average for the largest segment in terms of value, pharmaceuticals not exposed to competition. However, prices have decreased in this segment since 2014 in relation to other countries. Between 2014 and 2015, prices in Sweden were reduced compared to other countries through several reviews. During 2018, in 8 out of 20 countries prices were higher than in Sweden and in 11 countries they were lower. For pharmaceuticals not exposed to competition, Sweden's index has fallen by about ten percentage points. About sixty per cent of this change relates to the change in exchange rates (the krona has become weaker), and about forty per cent relates to changes in list prices.

The segment for pharmaceuticals that are exposed to competition includes all pharmaceutical groups in the selection that were included in the generic substitution system in 2018. In Sweden, pharmaceuticals within this system comprise approximately 60 per cent of the total pharmaceuticals use in volume, but only 20 per cent of the value. Sweden has low prices for these pharmaceuticals and only Denmark has lower prices than Sweden. Between 2014 and 2018, Sweden's prices have fallen by about 25 percentage points. In 2018, Sweden's prices were almost 75 per cent lower than the average for pharmaceuticals not exposed to competition.

TLV has conducted an in-depth analysis of the life cycle of pharmaceuticals. This analysis shows that Sweden's prices are on a par with the average when pharmaceuticals are launched. However, during the period when pharmaceuticals are between five and 15 years old, Sweden's prices are higher than the average. For

the pharmaceuticals that are between 15 and 20 years old, prices in Sweden fall to a level that is considerably lower than the average.

*Figure 1: Sweden's prices in relation to the average for pharmaceuticals grouped by year for market approval, based on data between 2014 and 2018*



*Source: IQVIA and TLV analysis. Note: Circle size shows sales value for the pharmaceutical groups in Sweden continuously for a period of 12 months up to and including March 2018*

A more in-depth analysis of pharmaceuticals that are older than 15 years shows that the price reductions on substances that are not substitutable are considerably lower compared to substances that are substitutable and which are part of the PV system.

## Terms and concepts

---

**ATC** – *Anatomical Therapeutic Chemical Classification, (ATC)* is a system for classifying pharmaceuticals. The ATC system consists of 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 Heart and cardiovascular system
- D Dermatological medicines
- G Genitourinary system and reproductive hormones
- H Systemic hormonal preparations, excluding reproductive hormones and insulins
- J Antiinfectives for systemic use
- L Antineoplastic and immunomodulating agents
- M Musculoskeletal system
- N Nervous system
- P Antiparasitic products, insecticides and repellents
- R Respiratory system
- S Sensory organs
- V Various ATC structures

**AIP - Pharmacy purchase price** – the pharmacy operator's purchase price in SEK.

**AUP - Pharmacy selling price** – the pharmacy operator's selling price in SEK.

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

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

**Ex-factory** – sales price from the marketing authorisation holder. Costs for transport from the factory plus taxes and mark-ups will be added.

**Generic pharmaceutical** – pharmaceuticals containing the same active substance, in the same dosage form and with the same strength, and which give the same medicinal effect.

**EPR - International reference price (IRP, EPR, ERP)** – pricing method where the price(s) of a pharmaceutical in one or more countries is considered in the national pricing of pharmaceuticals. Common synonyms are international reference pricing (IRP), *external price reference* (EPR) or *external reference pricing* (ERP). It could also be called simply reference pricing. The pricing method can be formal or informal/supporting, in combination with another method (e.g. assessment of benefit or value). Certain countries employ the concept of *internal* reference pricing, which is why in some literature, the acronym IRP is used differently than in this report.

**ERP** – see *EPR*

**INN - Generic name** – describes the chemical name of a substance. INN stands for *international non-proprietary name*. The purpose of the generic name is to enable brand name-independent communication of pharmaceutical substances. Generic names are established by various countries and by the WHO.

**IRP** – see *EPR*

**List price** – Price that is formally paid, regardless of discounts or bonuses. Equivalent to AIP in Sweden.

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

**Managed Entry Agreement** – see *Collateral agreement*.

**Managed introduction** – in Sweden called *National managed introduction of new pharmaceutical products* and is developed by the NT Council. Sweden's county council and regional authorities are collaborating on which new medicinal products should be introduced in health care.

**Originator pharmaceutical product** – the first pharmaceutical on the market that contains a particular active substance. These pharmaceuticals are under patent protection and are thus not exposed to competition from generic equivalents until patent protection expires.

**PV - Product-of-the-month** – Products-of-the-month are the generic substitutable pharmaceuticals that have the lowest price and that the pharmacies must offer their customers when they replace pharmaceuticals. Each month, the product in each package size group that has the lowest unit sales price and that the pharmaceutical company has confirmed can be provided to the entire market with a sufficient sustainability for the entire pricing period price becomes the product-of-the-month.

**PV system** – see *Product of the month*.

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

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

**Cross-sectional price index** – the same product needs to be available in several countries to be included in any of the countries' price indices. The threshold, referred to as matching degree, has been set at 40 percent in those cases where cross-sectional 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 those countries that do not have sales of one year of a pharmaceutical that is available in Sweden, Swedish prices are used instead.

**Relative prices** – prices in relation to average prices. If relative prices in Sweden increase, this means that Sweden has become more expensive in relation to average prices. This may be because Sweden's prices have increased, or that other countries have lowered their prices and Sweden has remained at the same level.

**Risk sharing agreement** – agreement where the final cost of a pharmaceutical product depends on future outcomes. Often used for new expensive pharmaceutical products where the therapeutic benefit is uncertain.

**Segment pharmaceuticals not exposed to competition** – includes products where competition between two different substitutable pharmaceuticals in Sweden has not arisen. Competitive conditions may nevertheless differ between the various countries in this price comparison.

**Segment pharmaceuticals exposed to competition** (in the product-of-the-month system) includes all pharmaceuticals available as substitutable pharmaceuticals for the product-of-the-month as per March 2017.

**Collateral agreement** – collective name for agreements that modify the list price, such as risk-sharing agreements, discount and rebate agreements. In Sweden, these agreements are concluded between the manufacturers and the county councils.

**Ceiling prices in substitutable groups** – the maximum accepted price (AIP/unit) of a pharmaceutical in a package size group.

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

**Rebate** – a form of discount that is paid retrospectively. In Sweden, manufacturers pay rebates to county councils through collateral agreements.

# 1 Introduction

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## 1.1 Assignment

The Dental and Pharmaceutical Benefits Agency, hereafter TLV, has a mandate to monitor and analyse the developments in the pharmaceutical, pharmacy and dental care markets in Sweden. One of TLV's aims is to develop value-based pricing in order to ensure that pharmaceuticals are cost effective throughout their entire life cycle. Part of this work involves setting Sweden's pharmaceutical prices and use in an international perspective. The regulation (2007:1206) with instructions to TLV, amongst other things, states that the agency has a mandate to monitor and analyse developments in other countries and take advantage of experiences, compare the price level in Sweden with prices in other countries for relevant products, and also monitor price developments in an international perspective. This report is part of the ongoing work and is the fifth report of its kind. This report was originally published in Swedish by TLV in Swedish December 2018.

The comparison covers pharmaceuticals not exposed to competition as well as pharmaceuticals exposed to competition. The report describes how the prices of prescription pharmaceuticals in Sweden relate to 19 other countries in Europe. For all countries, see the table below.

*Table 1. Countries compared in the report*

Belgium	Portugal
Denmark	Switzerland
Finland	Slovakia
France	Spain
Greece	UK
Ireland	Sweden
Italy	Czech Rep.
Netherlands	Germany
Norway	Hungary
Poland	Austria

The purpose of the report is to analyse the Swedish prices in an international perspective. In addition, the dynamics are examined in terms of price, volume and exchange rate, factors that affect the Swedish prices in relation to other countries.

### 1.1.1 Delimitation

The mandate does not include determining whether Swedish pharmaceutical prices are at the desired level or suggest changes to potentially reach a desired level. This report primarily analyses the outpatient market, and therefore pharmaceuticals sold within inpatient care have limited coverage in this report.

## 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. A more comprehensive description of the methodology, sensitivity analyses and previous studies can be found in *Appendix 1: Sensitivity analysis and methodology*. Then follows a section on the pharmaceuticals market in general and information on pricing and reimbursement systems for the countries in the sample. In *Appendix 2: Pricing and reimbursement systems*, there are detailed descriptions of the systems in all countries.

The *Results* section is divided into three sections. First, there is an in-depth study on the life cycle of pharmaceuticals, where prices are analysed according to the age of the pharmaceutical. Then there is a more detailed description of pharmaceuticals not exposed to competition (outside the generic substitution system) and then pharmaceuticals exposed to competition (within the generic substitution system).

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

## 1.3 Methodology and data

### 1.3.1 Exchange rate

In a historical perspective, the Swedish krona has been weak during 2018. In order to obtain a more balanced overview of the Swedish relative prices, exchange rates have therefore been calculated as a three-year rolling average. This differs from the reports of previous years when the average rates during the first quarter were used. See the section *Sensitivity analyses*, and subheading *Exchange rate*. In the sensitivity analysis, the outcome is also tested for other exchange rates.

Unlike previous reports, exchange rates have been allowed to vary between the years in this report. This means that the average value of the exchange rate for the first quarter of 2015 to the first quarter of 2018 has been used for the 2018 index. The index figures and prices during 2014 in this report are based on the average exchange rate for the first quarter of 2011 to the first quarter of 2014. For earlier years, the previous year's exchange rates have been kept constant over time.

### 1.3.2 Description of data sources

Method and data selection are briefly described here, and in greater detail under *Methodology* in *Appendix 1*.

The sample consists of the prescription human pharmaceuticals in Sweden showing the highest sales and covered by pharmaceutical benefits, totalling almost 750 substances. The market has been divided into pharmaceuticals not exposed to competition and pharmaceuticals exposed to competition, in three segments.

- Originator pharmaceutical products with patents (243 substances)

- Originator pharmaceutical products without patents but not exposed to competition (210 substances)
- Pharmaceuticals (generic) exposed to competition (299 substances)

Together, these pharmaceuticals account for about 97 per cent of sales in Sweden. The price index reflects the list prices in other countries and is based on the pharmacy's purchase price (AIP) or equivalent. Discounts on list prices in other countries and reimbursements from collateral agreements in Sweden are not included in the decision data. A product is defined as a pharmaceutical with the same substance, dosage form and strength. The price is calculated as cost per dose.

The price index has been calculated using a Laspeyres index, where prices are weighted with the sales volumes in Sweden. In the sensitivity analysis in *Appendix 1*, the index is also weighted with the volumes in other countries.

The report is mainly based on bilateral indices, which compare pharmaceutical prices in an individual country that matches those also in Sweden. Pharmaceuticals that show very low sales in relation to Swedish sales have been excluded. When calculating the price index in many countries (cross-sectional index), a pharmaceutical must have sales in eight countries to be included in the price basket.

TLV has used price and sales statistics from IQVIA for the first quarters of 2014, 2015, 2016, 2017 and 2018. The price level in Sweden is compared with 19 other European countries. The report is based on national list prices at pharmacy purchase price (AIP).

## 2 The pharmaceuticals market

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### 2.1 Market overview

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

Pharmaceuticals have annual global sales of around SEK 7,266 billion, calculated as the price from the manufacturer<sup>1</sup>. North America dominates the pharmaceutical market and represents about 48 per cent of the world market. Europe in its broadest sense represents about 22 per cent. Africa, Asia and Australia together account for just over 17 per cent, Japan represents just over 8 per cent of the world market and Latin America just over 5 per cent.

For the 20 countries in the study, the total sales amount to SEK 1,764 billion at the AIP level for both outpatient and inpatient care, March 2017 to March 2018. The total outpatient sales for the countries amount to SEK 1,081 billion for the period, accounting for 60 per cent of the total sales value<sup>2</sup>.

The total population of the 20 countries in the study amounts to about 483 million inhabitants<sup>3</sup>. The five largest countries in terms of population (Germany, France, United Kingdom, Italy and Spain) together account for almost 66 per cent of the population base. These five countries account for about 69 per cent of the 20 countries' total sales in the analysis at pharmacy purchase price (hereafter called AIP). Sweden's share of the population is 2 per cent, and its share of the total sales is just under 4 per cent.

#### 2.1.1 Outpatient and inpatient care

The analyses in this report are mainly based on pharmaceutical prices in outpatient care, which means that the pharmaceuticals are collected at pharmacies. In some

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<sup>1</sup> EFPIA, The Pharmaceutical Industry in Figures 2018, states that global sales amount to EUR 754,555 million. Calculation to SEK according to the average exchange rate (9.63) in 2017.

EFPIA (2018) The Pharmaceutical Industry in Figures, Key data 2018.  
[https://www.efpia.eu/media/361960/efpia-pharmafigures2018\\_v07-hq.pdf](https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf)

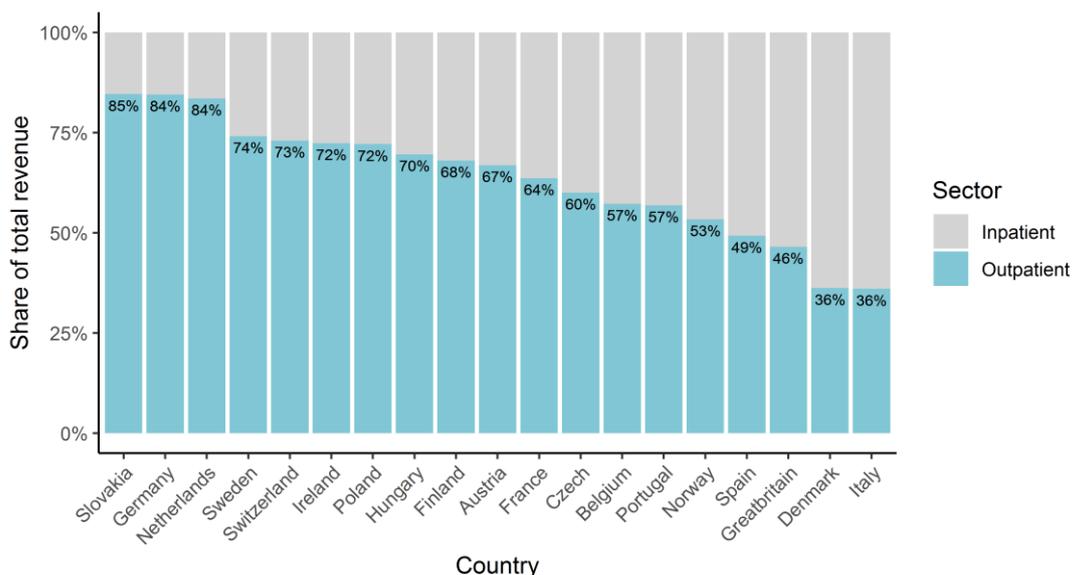
<sup>2</sup> IQVIA and TLV Analysis

<sup>3</sup> Eurostat (2015)

countries, some pharmaceuticals are largely managed within inpatient care, which in Sweden are predominantly managed via prescription in outpatient care. Some caution should be exercised when comparing data from outpatient care only. The choice of pharmaceutical management, i.e. by prescription in outpatient care or at a hospital with inpatient care, makes this kind of comparisons difficult without knowledge of specific national conditions regarding pharmaceutical management.

The figure below shows the percentage of outpatient and inpatient management by sales value. On average, these 19 countries manage over 60 per cent of the total sales within the context of outpatient care. Denmark, Italy, the United Kingdom and Spain are the countries that have a relatively small sales value within outpatient care and a significantly higher relative percentage that is managed within inpatient care. In Sweden, approximately three quarters are managed by prescriptions within outpatient care, and one quarter is managed within inpatient care.

Figure 3: Percentage of sales value in AIP sold within inpatient and outpatient care per country, rolling 12 months through March 2018.



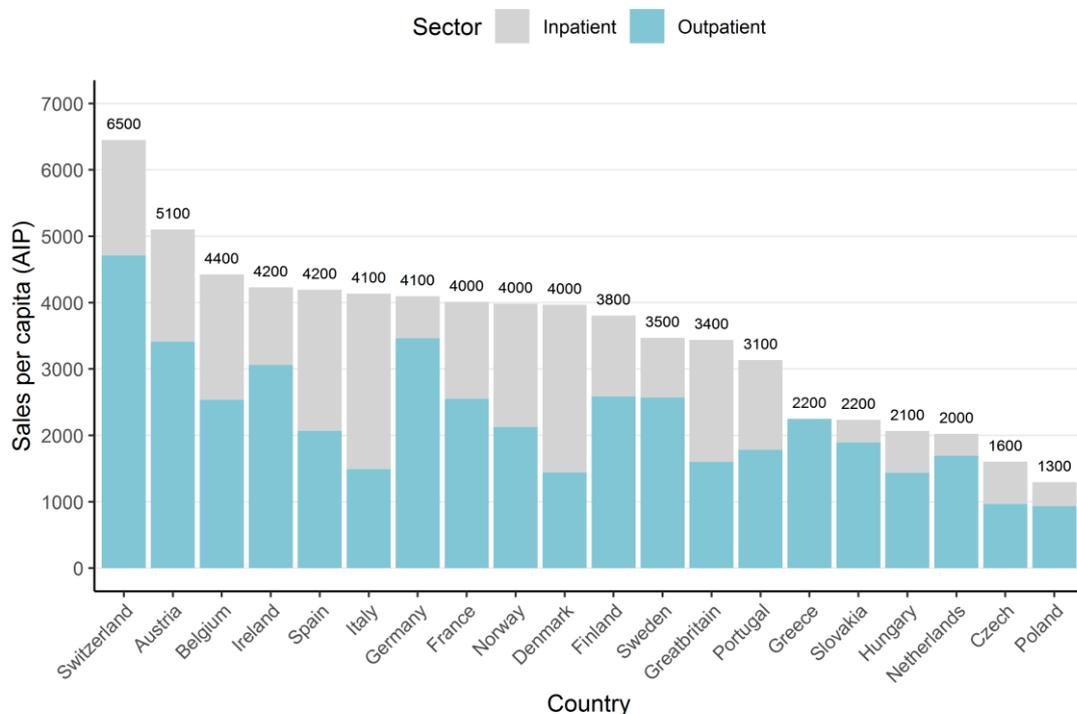
Note: Greece is excluded because hospital data is missing

Source: IQVIA and TLV analysis.

The following figure shows outpatient and inpatient pharmaceutical sales per capita in Europe. The average amounts to approximately SEK 3,500. The total sales value per inhabitant is highest in Switzerland (approximately SEK 6,500 per inhabitant), followed by Austria (SEK 5,100 per inhabitant). Sweden has the twelfth highest sales of all countries with approximately SEK 3,500 per capita.

Based on total sales value per capita, our Nordic neighbours Denmark, Norway and Finland have slightly higher costs compared to Sweden.

Figure 2: Sales value in SEK AIP, which is sold within inpatient and outpatient care per country, rolling 12 months through March 2018. Rounded to even hundreds.



Note: Inpatient data is missing for Greece

Source: IQVIA and TLV analysis.

The analysis only includes products with sales within the Swedish outpatient care. The sample was limited to prescription pharmaceuticals within outpatient care because it is these pharmaceuticals that TLV sets prices for and can influence. The products in inpatient care also have less transparent prices, which makes this type of analysis more difficult.

There may be variations in how countries choose to treat the same disease. One difference could be how they handle what is distributed through prescription, and what is managed within the context of inpatient care. Another difference could be variations in drug therapies, which could mean that a disease is treated with different pharmaceuticals than those used for treatment in Sweden. In addition, 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 to the same extent in the comparison countries. The calculation of the weighted price index covering all countries is affected by the mix of pharmaceuticals available in the different countries. Products sold by prescription in Sweden may not be sold by prescription in other countries. Such products will then not be included in the index calculation.

### 2.1.2 Pricing models

Prices of pharmaceuticals can either be set freely by the market or by direct or indirect regulation. A frequently used method is to consider the price level in several reference countries (reference pricing) or to base pricing on appraised values or profitability.

*Table 1 Different pricing systems*

1	Alternative method to international reference pricing	a) Value-based pricing	b) Indirect price control by assessing value and profitability	c) Free pricing
2	International reference pricing (IRP)	a) Formal	b) Informal in combination with another method (e.g. assessment of benefit or value)	

Reference pricing, which is the most common method in Europe, can be formal or informal/supporting. This means that the average, the median or the maximum price that is calculated governs the set price either directly, or it constitutes a level that is considered during negotiation, during procurement or that forms part of a wider supplementary health-economic assessment.

The number of countries in a price basket varies greatly within Europe, from 3 to 31 countries. Consequently, this affects what effect an individual country's price or price range will have on a price basket in another country. The direct or indirect strength of the price impact also varies depending on whether the country applies some form of supplementary assessment in addition to international reference pricing. Also, of great importance is whether a country considers the lowest price or the average price among the prices in a reference basket, see figure below. For a more detailed description of the pricing system, see Appendix 2: Pricing and reimbursement systems.

There are several variants for generic substitution systems linked to the lowest price over a period of time. Examples of this are as follows:

- Denmark uses periods of two weeks,
- Sweden, with the product-of-the-month, has a period of one month,
- The Netherlands has a period of 3, 6, 12 or 24 months and
- Finland has a system with the product-of-the-month for three months. However, in Finland, prices may vary during the period.

The systems for generic substitution in these countries differ, but the basic idea is the same. The product with the lowest price within a defined substitution group is the pharmaceutical that is primarily sold in pharmacies during a set period. Norway applies a stepped pricing model for generic pharmaceuticals. This model involves linking the price to the time after a different number of competitors have entered the market and to sales volume. Other examples are Austria, France and Ireland, which connect price reduction of the original and generic pharmaceuticals to certain periods of time after competing pharmaceuticals have entered the market.

Most of the countries have some form of supplementary pricing and reimbursement management in addition to traditional pricing. In some cases, this applies to the entire pricing through general discounts, but it is more common for measures to be applied to specific products. What in Sweden is referred to as “sidoöverenskom-melser” (“collateral agreements”) falls under the broader concept of *managed entry agreements* (MEA) internationally. An MEA can be anything from special financial agreements with refunds, rebates, discounts, price-volume agreements and risk sharing to different variants of managed introduction.

Portugal, Germany and Spain are examples of countries with general discount systems that are not seen in list prices. Lack of complete information on discounts is a weakness in all price surveys. However, analysis of change over time and – specifically in this report – a comparison of the development of the same products between 2014 and 2018 is a clear advantage. Assuming that any discounts are at about the same level from one year to the next gives a good comparison of the relative price development between different countries.

For further information about the pricing models, please see Appendix 1 and 2, which are intended to improve understanding of the pricing and reimbursement systems in the 20 countries analysed in TLV’s international price comparison.

## 2.2 Descriptive statistics

The table below shows how much of Sweden's sales are covered by the data that forms the basis for the analysis. The data set for this report comes from IQVIA.

*Table 2. Sales of pharmaceuticals at the AIP level that are part of the sample for different segments as well as total sales, MSEK, rolling for 12 months.*

Segment	Mar 2018 (AIP MSEK)	Mar 2017 (AIP MSEK)	Mar 2016 (AIP MSEK)	Mar 2015 (AIP MSEK)	Mar 2014 (AIP MSEK)
Not exposed to competition	17.56	16.18	14.23	13.08	11.45
Exposed to competition	4.19	4.29	4.81	5.42	5.09
Total in the sample	21.75	20.48	19.04	18.50	16.54
Total sales of pharmaceuticals in the benefits scheme in Sweden	22.50	21.28	20.02	18.93	18.51
Proportion of sales in sample in relation to Swedish sales	97%	96%	95%	98%	89%

The sales value does not cover the total prescription sales of pharmaceuticals in Sweden in the outpatient market. The data set from IQVIA contains the approximately 750 substances that have the highest sales in Sweden in 2018 and substances with lower are therefore not included.

## 3 Results

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In this section, the results of the comparison of Sweden's pharmaceutical prices in relation to other countries are presented. The results are presented in three sections:

- Prices over the pharmaceutical's life cycle
- Pharmaceuticals not exposed to competition
- Pharmaceuticals exposed to competition

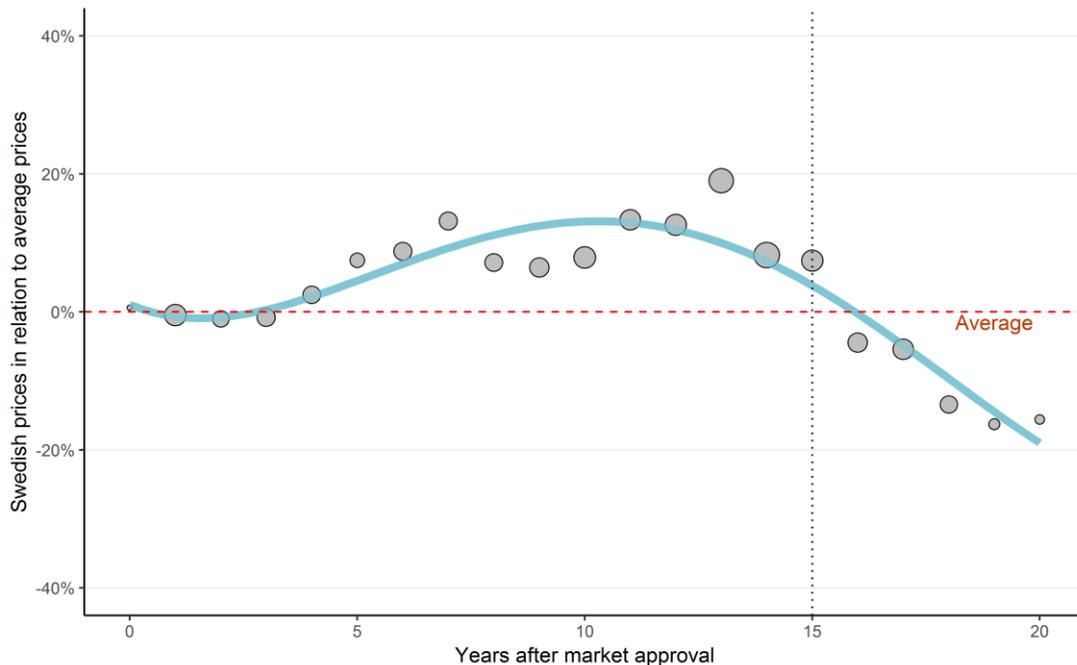
A pharmaceutical's life cycle has been analysed from the time when the pharmaceuticals received market approval. The division of pharmaceuticals between exposed and not exposed to competition is made against the background that many countries treat pharmaceutical pricing differently depending on their potential for substitution. In Sweden, a pharmaceutical is defined as substitutable if it is included in the product-of-the-month system. The fact that a pharmaceutical is not substitutable may be due to the temporary monopolies that patents provide, or that the pharmaceutical is not considered substitutable on medical grounds. An example of a pharmaceutical that is not considered substitutable even though it lacks patent protection is the drug gabapentin that is used to treat epilepsy.

### 3.1 Prices dynamic over the life cycle of a pharmaceutical

This section examines how Sweden's prices compare with the prices in other European countries based on the launch year. This analysis covers the entire period from 2014 to 2018 and includes pharmaceuticals both exposed and not exposed to competition. The price is important not only during the launch but over the entire life cycle of a pharmaceutical. Price dynamics mean that innovations will benefit consumers, as the consumer surplus increases when consumers get a better product at the same price, or when they get the same product at a lower price. The fact that the price of older pharmaceuticals is falling may have a major impact on the total pharmaceutical costs.

*Figure 3* below shows Sweden's pharmaceutical prices for each year after European market approval, compared with the average in the comparison countries (up to 20 years after launch). The figure should be interpreted as showing that Sweden's pharmaceutical prices are in line with the average of the comparison countries during the first five years. Between years 5 and 15, Sweden has more expensive medicines, with or without competition. After year 15, marked with a vertically dotted line, Swedish prices fall to below the average.

Figure 3: Sweden's relative pharmaceutical prices compared to the average price for the report's 20 European countries, per year after market approval.



Source: IQVIA and TLV analysis. The red line shows the average prices for 20 European countries. The positions of the circles show 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 years 2014–2018.

The size of the circles indicates how large the sales value is for the pharmaceuticals in the age grouping. The age grouping is based on market approval and not introduction in Sweden. Pharmaceuticals that are 10 to 15 years old account for relatively large expenditure in Sweden (larger circles).

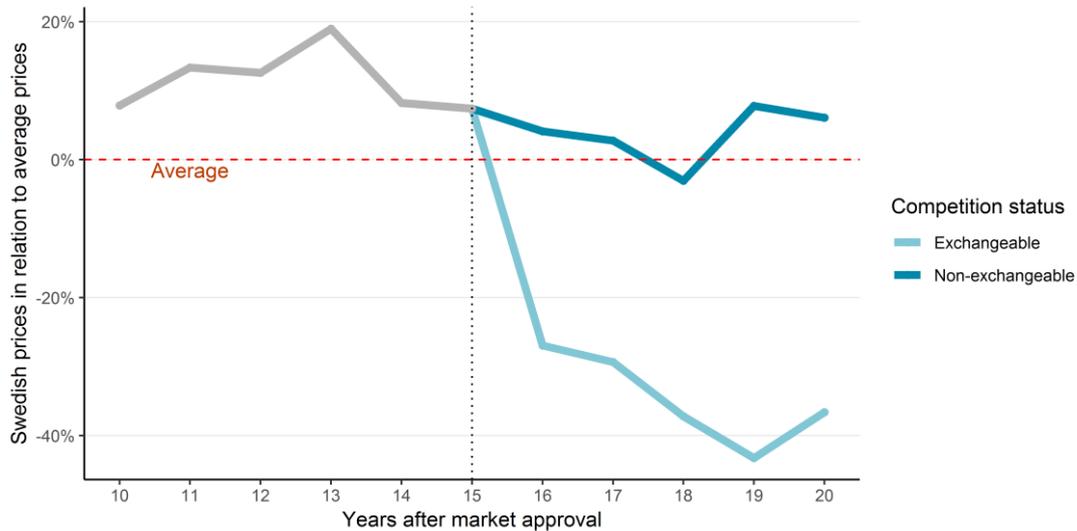
The figure shows that Sweden has relatively competitive prices at launch and for a few years afterwards. After five years, Swedish prices start to rise to become higher than average. On the other hand, after 15 years, Swedish prices fall to below average.

### 3.1.1 The effect of substitutability

Sweden has relatively low prices for pharmaceuticals exposed to competition. The product-of-the-month system has a well-functioning price-pressing effect. However, not all pharmaceuticals are substitutable, and in the product-of-the-month system, after patent expiry. Even within the period-of-the-month-system there are pharmaceuticals that cannot be substituted at pharmacies and are then classified as so-called EK groups. In this segment of pharmaceuticals, Sweden generally has a higher price than the comparison countries.

The figure below shows the price dynamics for Sweden before and after year 15, which often means the end of patent protection for pharmaceuticals.

Figure 4: Sweden's relative pharmaceutical prices at year 15 of a pharmaceutical compared with the average price for the report's 20 European countries, per year following market approval.



Source: IQVIA and TLV analysis. The axis starts at 10 years. After 15 years, the trend lines are divided into pharmaceuticals that are substitutable or non-substitutable. The line that is red, horizontal and dashed shows average prices for 20 European countries. Sales data in 2018.

The figure shows that Sweden's prices are about 10 to 20 per cent above the average for the period of 10 to 15 years following market approval, which is represented by the grey line.

After year 15, two lines are shown. The light-blue shows non-substitutable pharmaceuticals (EK groups) and it falls towards the approximate average. An explanation for Sweden's relative improvement in non-substitutable pharmaceuticals is the 15-year rule that began to apply in 2015. The 15-year rule means that pharmaceuticals that do not face generic competition 15 years after market approval must have a price reduction of 7.5 per cent.

On the other hand, the pharmaceuticals that face generic competition fall rapidly in price relative to other countries. In the figure above, this pattern is shown in the dark-blue line. The estimate shows that already after three years the product-of-the-month system gives Sweden about 40 per cent lower prices than the average of the 20 countries included in the comparison.

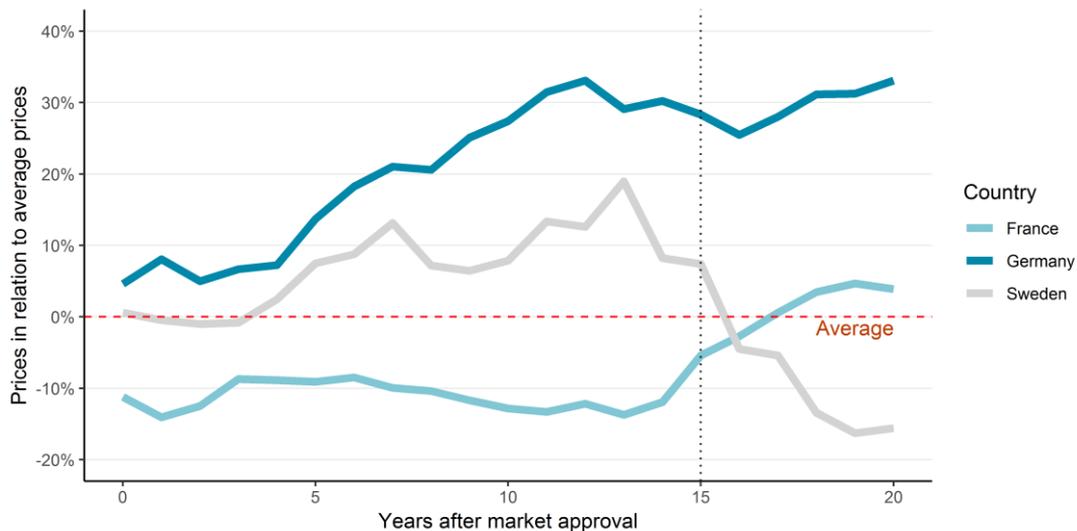
### 3.1.2 Price dynamics in Germany and France

In the figures above, Sweden's prices are compared with the average for the 20 European countries. However, price dynamics differ between countries. In Appendix 2: Pricing and reimbursement systems there are descriptions of the pricing systems of the participating countries, where, in particular, the pricing systems of Germany, France and the United Kingdom are examined. Germany and France have been chosen as in-depth areas because in some respects the countries are each other's opposites: Germany is known to have high prices but also early

market entry and high availability (“market entry” and “market access”), while France has lower prices but at the same time later market entry/lower availability.

The figure below shows how the German and French prices relate to the prices in Sweden and the average in other countries over the life cycle.

*Figure 5: The relative pharmaceutical prices in France, Germany and Sweden in comparison with the average price for the report's 20 European countries, per year following market approval, outpatient care.*

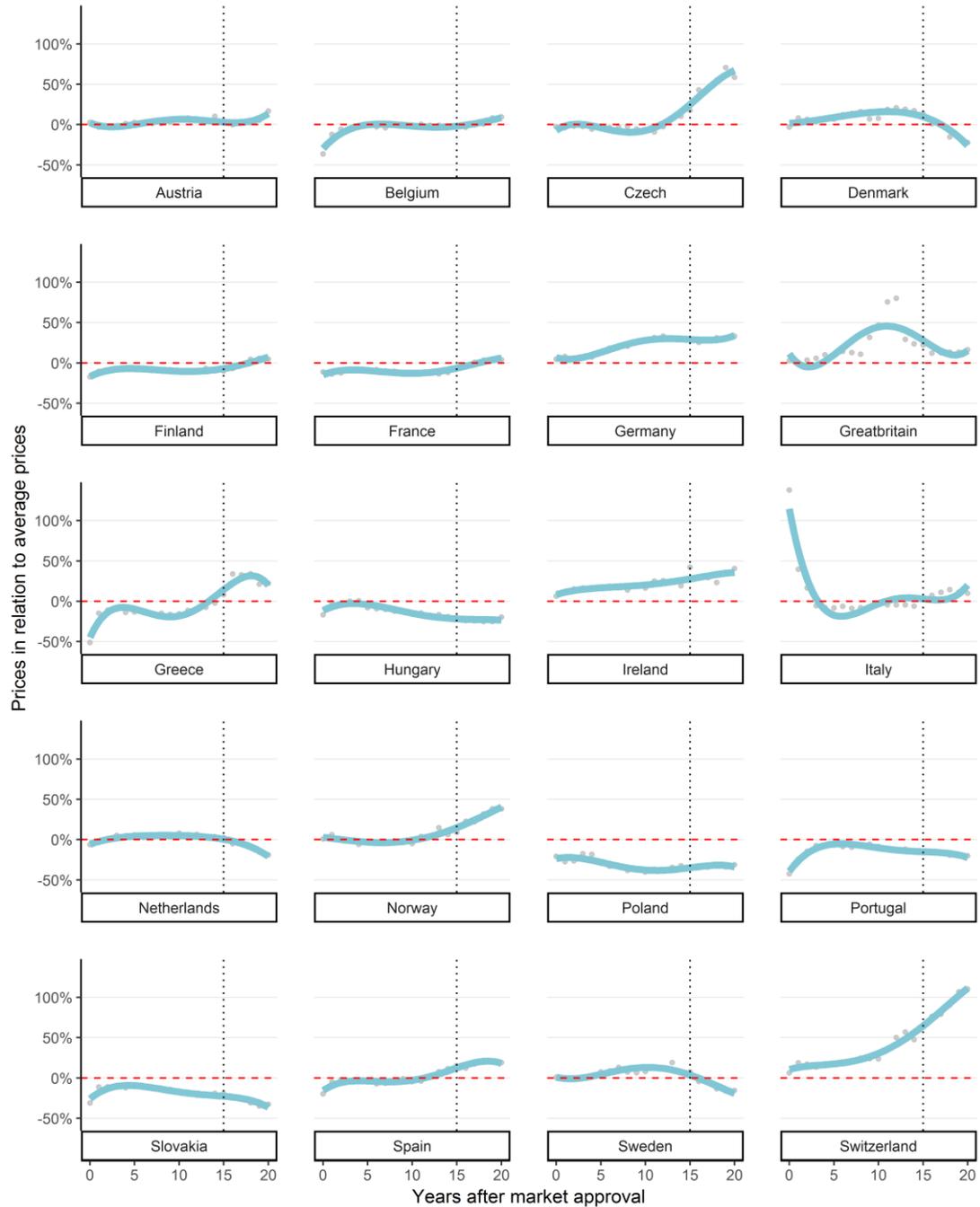


Source: IQVIA and TLV analysis. The red, horizontal, dashed line shows average prices for 20 European countries.

At launch, Germany has a higher price index than Sweden and France. Germany then exhibits price dynamics where its prices gradually become relatively more expensive. France exhibits a reverse pattern. It has a lower price index than Sweden and Germany at launch. For the age groupings 5 to 15 years, the difference in the index gradually increases compared with the other two countries. However, for pharmaceuticals 16 years and older, Sweden has lower prices than France. No account is taken of possible discounts on pharmaceuticals.

The development of price over the life cycle can partly be explained by differences in the pricing and reimbursement systems in the countries. Germany has a system with free price and no restrictions on use during the first year. France has a pricing system with an emphasis on budget and volume control, and with recurring pharmaceutical reviews. On the other hand, Germany has faster market entry/higher availability than France. See Appendix 2: Pricing and reimbursement systems for a more detailed description of pricing systems in the countries.

Figure 6: Relative list prices of all countries compared to the average price for the report's 20 European countries, per year following market approval, outpatient care.



Source: IQVIA and TLV analysis.

Note: Norway's price development should be interpreted with caution since list prices for pharmaceuticals exposed to competition often differ significantly from actual transaction prices (see the section on Nordic overview for more information).

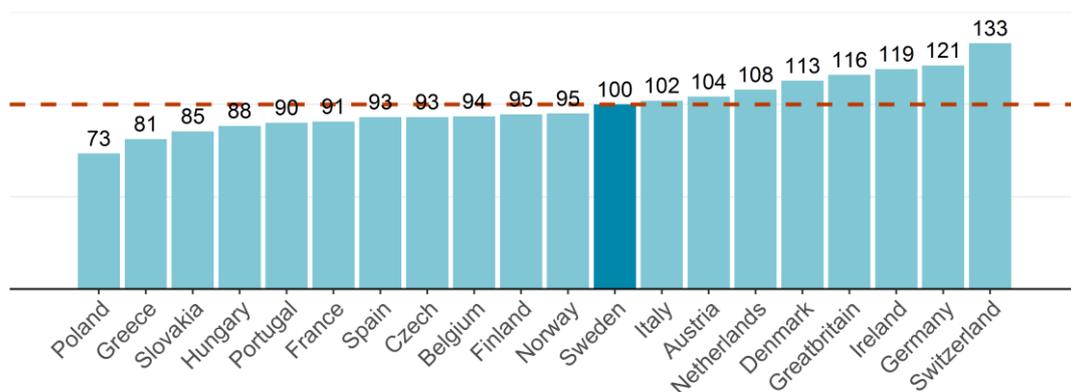
## 3.2 Pharmaceuticals not exposed to competition

Pharmaceuticals that are considered non-substitutable by the Swedish Medical Products Agency are included in the segment for pharmaceuticals not exposed to competition. Sweden and other countries have different pricing systems to control the costs of pharmaceuticals, which is necessary because the use of pharmaceuticals is largely financed from public funds. In Sweden, so-called value-based pricing is used, which means that TLV makes health-economic evaluations of pharmaceuticals before they are subsidised within the framework of the high-cost protection scheme. Several countries also use different types of reimbursement models that reduce the actual costs of pharmaceuticals compared to list prices.

### 3.2.1 Price index 2018

Analysis of prices of pharmaceuticals not exposed to competition reveals that there are significant differences between the countries included in the comparison. *Figure 7* presents the results for 2018. Sweden is ranked 12 out of 20 countries, which means that Sweden has lower prices than eight of the countries and higher prices than 11 of the countries.

*Figure 7: Bilateral price index for pharmaceuticals not exposed to competition in 2018, Sweden = 100, prices 2018 Q1, volumes running 12-month period through March 2018, 3 year average exchange rate*



Source: IQVIA and TLV analysis.

The figure shows a bilateral price index where Sweden's prices during the first quarter of 2018 are compared with the prices in other countries during the same period. The fact that Switzerland has an index of 133 means that its prices are on average 33 percent higher than Sweden's prices for pharmaceuticals used in both countries. On the other hand, prices in Poland are about a quarter lower than Sweden's prices.

The exchange rate is a factor that affects the level of the index and Sweden's relative position in the ranking. Using the exchange rate from the first quarter of 2018,

Sweden would be in position 11 instead of 12. The report uses an average exchange rate over three years, which probably gives a more robust measure of the relative differences in price between countries.

Calculated as a cross-sectional index, the average price index is 100.9 in the first quarter of 2018. On average, the prices in the other countries are therefore almost 1 per cent higher than the Swedish prices. If pharmaceuticals covered by collateral agreement in Sweden are excluded, the average cross-sectional index amounts to 99 instead. This means that Sweden has slightly lower prices for pharmaceuticals that are covered by collateral agreements and slightly higher prices for pharmaceuticals that are not covered by collateral agreements.

### 3.2.2 Degree of matching

The degree of matching illustrates what proportion of the pharmaceuticals in the sample that are available in both Sweden and other countries. The focus here is only pharmaceuticals that are available in both Sweden and other countries.

Pharmaceuticals sold below a so-called bagatelle limit abroad have been excluded.

Sweden has a total of 1,501 products in the sample for this segment (from 380 originator pharmaceutical products with and without patents). These pharmaceuticals are used as base in the comparison with the prices in other countries. Sales of pharmaceutical forms in other countries that do not match those found in Sweden have therefore been excluded (even if the substance itself is found in other countries). The number of pharmaceuticals that are available in Sweden (counted as substance, dosage form and strength) is therefore the maximum number of pharmaceuticals.

On average, the degree of matching is highest in Germany (69 percent), followed by a group of countries such as Austria, Finland, the UK, Switzerland and the Netherlands with a degree of matching between 53 and 57 per cent. The lowest degree of matching is with countries such as Portugal, Poland, Greece and Hungary, with just over 30 per cent. The degree of matching with our Nordic neighbours, Denmark and Norway, is about 50 per cent. The bilateral indices only compare prices where the same pharmaceuticals are available in both Sweden and the comparison country. With Germany, the price comparison can be based on 69 percent of the pharmaceuticals available in Sweden, while with Portugal the comparison is based on just 31 percent of Swedish pharmaceuticals. Bilateral indices can therefore only compare each country with Sweden, not between other countries by themselves. Of the ATC-1 level pharmaceutical groups that have the largest sales in the patented segment in Sweden, the degree of matching is highest within ATC A (Alimentary tract and metabolism) and ATC R (respiratory system). On average, 58 percent of the Swedish pharmaceuticals are found within these groups. The degree of matching is lowest within ATC B (blood-forming organs) and ATC J (anti-infectives for systemic use).

It may be relevant to consider differences in the degree of matching between countries when examining differences in a bilateral price index more closely. A high degree of matching and a pharmaceutical use similar to Sweden means that the price comparison becomes more robust. Comparisons with countries with very low

degrees of matching will be more difficult to generalise, since the comparison is only relevant for the few products that are common.

Figure 8: Degree of matching for pharmaceuticals not exposed to competition, Q1 2018

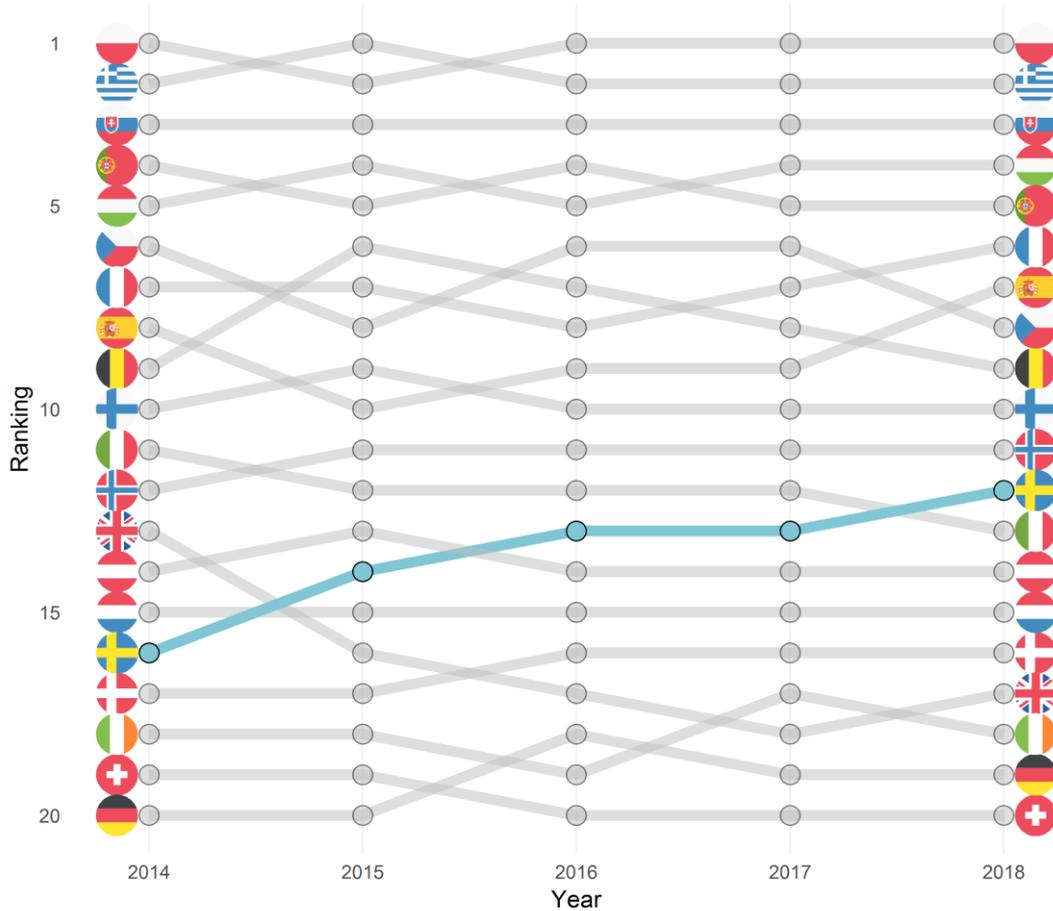
	A	B	J	L	N	R	Other	Average
Sweden	100%	100%	100%	100%	100%	100%	100%	100%
Germany	73%	62%	66%	87%	66%	65%	64%	69%
Austria	66%	56%	58%	76%	58%	53%	45%	58%
Finland	64%	55%	25%	61%	60%	66%	53%	56%
Greatbritain	75%	40%	55%	28%	64%	64%	60%	55%
Switzerland	55%	42%	51%	73%	52%	55%	49%	54%
Netherlands	76%	54%	59%	32%	62%	66%	47%	53%
Norway	69%	51%	39%	12%	60%	73%	59%	51%
Ireland	60%	41%	29%	56%	51%	55%	51%	50%
France	45%	35%	52%	67%	48%	54%	42%	49%
Denmark	61%	25%	26%	21%	65%	66%	51%	47%
Belgium	51%	20%	41%	36%	41%	47%	42%	40%
Slovakia	54%	38%	28%	52%	38%	54%	29%	39%
Spain	44%	17%	16%	22%	52%	56%	40%	38%
Italy	48%	30%	15%	20%	46%	55%	42%	38%
Czech	49%	23%	18%	34%	42%	51%	31%	35%
Hungary	40%	27%	25%	38%	33%	45%	32%	34%
Poland	32%	19%	17%	23%	41%	49%	37%	33%
Greece	54%	24%	17%	22%	37%	45%	33%	33%
Portugal	44%	15%	10%	10%	42%	45%	36%	31%
Unweighted average	58%	39%	37%	43%	53%	58%	47%	48%

Source: IQVIA and TLV analysis.

### 3.2.3 Historical development of the price index

Sweden's prices in pharmaceuticals not exposed to competition have declined in relation to other countries. In 2018, Sweden is in 12th position in the ranking, as 11 countries have lower prices and eight countries have higher prices. In 2014, Sweden was in 16th position, when only four countries had higher prices. This means that prices in Sweden have decreased since 2014, since a country climbs in the ranking list when prices fall in relation to other countries. Figure 9 shows the development between 2014 and 2018 for all countries included in the comparison.

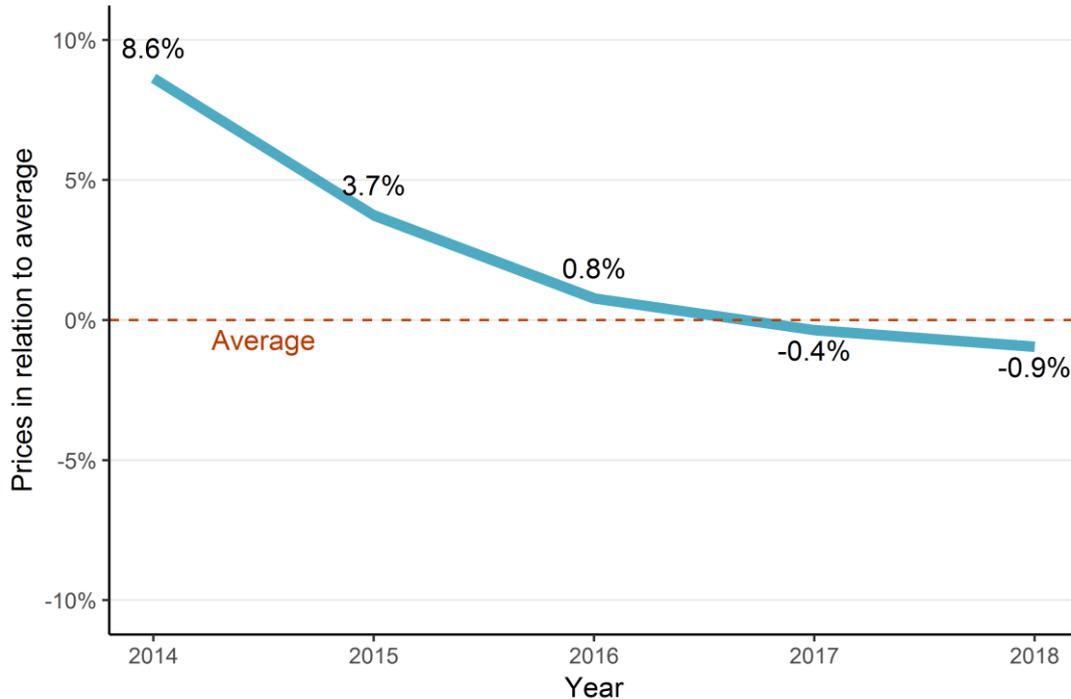
Figure 9: Development of the bilateral price index over time, 2014 – 2018. Rank 1 means that the country has the lowest prices, running 3-years of average exchange rates per year.



Source: IQVIA and TLV analysis.

Figure 9 shows that Sweden's prices have decreased compared with other countries since 2014. In order to have a better overview of the development, it is also interesting to look at the size of this change. *figure 10* shows the percentage deviation between the prices in Sweden and the average prices in other countries. The calculation is based on a cross-sectional index, which means that a pharmaceutical must be available in at least eight countries in order to be included in the comparison.

Figure 10: Sweden's relative prices compared to the average per year calculated as cross-sectional index. Pharmaceuticals not exposed to competition, running 3-years of average exchange rates each year.



Source: IQVIA and TLV analysis.

The figure shows that Sweden's prices in 2014 were 8.6 per cent higher than the average for all countries. Over time, Sweden's prices have gradually decreased by 9.6 percentage points until the first quarter of 2018, when Sweden's prices were instead about 1 per cent lower than the average. As shown below, this development is due to a combination of changes in prices, volumes, exchange rates and product range.

### 3.2.4 Drivers of the index

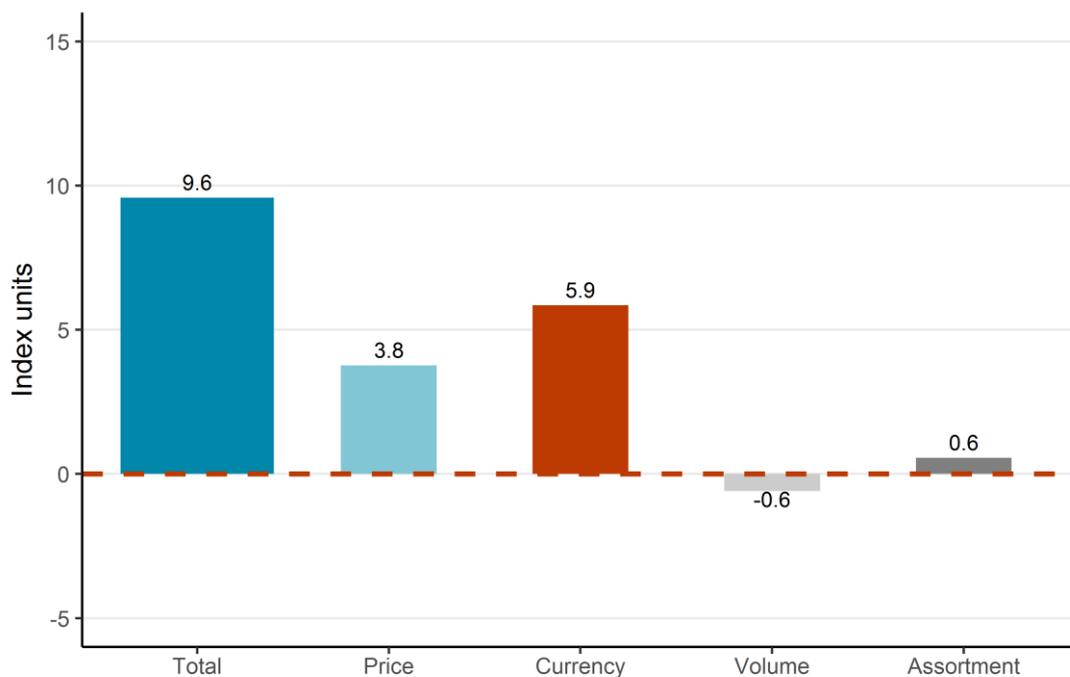
There are several factors that influence the comparison of pharmaceutical prices between countries over time. In this analysis, the development of the price index has been divided into changes in price, currency and product mix.

- The price change captures the effect from the change in price per unit of a pharmaceutical in a country's own currency. If the price per unit increases from SEK 100 to SEK 120 in Sweden and at the same time remains unchanged in the comparison country, the change in price is 20 per cent, given that the exchange rate is unchanged.
- The currency change captures the effect of exchange rate development between different currencies. If the rate for the euro moves from SEK 10 to 11, the cost

has decreased in Sweden relative to countries using the euro, given that the prices in the local currencies are unchanged.

- The volume change captures the effect of new products being added and changes in the distribution of use between products in Sweden. If Sweden changes its use over time to products whose prices are lower in Sweden compared to other countries, Sweden's index will decrease.
- In addition, there will be a change in the product range consisting of the net effect of newly added and discontinued pharmaceuticals. This effect is calculated as a residual of the other components.

*Figure 11: Change in cross-sectional index for pharmaceuticals not exposed to competition between 2014 and 2018, broken down by changes in price, currency, volume and product range.*



Source: IQVIA and TLV analysis.

As shown in *Figure 10*, the price index in Sweden was approximately 8.6 per cent higher than the average for all countries in the first quarter of 2014. During the corresponding period in 2018, the index was just under 1 per cent lower. This corresponds to an index increase abroad of approximately 9.6 index units during the period (from 92.9 to 100.9).

The figure above shows the drivers for this change. Approximately 40 per cent of this change is explained by price changes and the remaining 60 per cent by currency fluctuations. On average, the development is not significantly affected by changes in volume or product range.

*Figure 11* shows that the price component has increased the cross-sectional index by just under 4 per cent, which means that foreign prices have increased in relation to the Swedish prices. This development is largely a consequence of extensive reassessments in Sweden at the end of 2014 and 2015 and the effects of the 15-year rule<sup>4</sup> having an impact from the latter part of 2014. Over time, the price effect for pharmaceuticals not exposed to competition is stable compared with other countries.

A weaker Swedish currency has increased the cross-sectional index by just under 6 per cent. This effect is only a result of currency fluctuations. If the Swedish currency gained strength to the same levels as in 2014, the index will fall correspondingly by 6 per cent without any change in prices in either Sweden or other countries. The weakening of the Swedish krona has therefore not been clearly reflected in increased prices within the framework of the Swedish system of value-based pricing. In this analysis, no account has been taken of the occurrence of rebates/discounts in either Sweden or other countries. On the other hand, prices have risen in Norway as a result of the weaker currency, as evident from *Figure 12*. However, a sustained weak Swedish currency over time may result in an upward pressure on Swedish prices, both for the existing product range and for new pharmaceuticals.

Since classified rebate levels or hidden prices is becoming more common both in Sweden and in other countries, an analysis involving discounts would be of interest. Such a comparison must be made at a highly aggregated level so as not to disclose underlying discounts or other classified information. This also means that products used in both inpatient and outpatient care need to be included in the analysis, which requires a greater selection of products than used in this report.

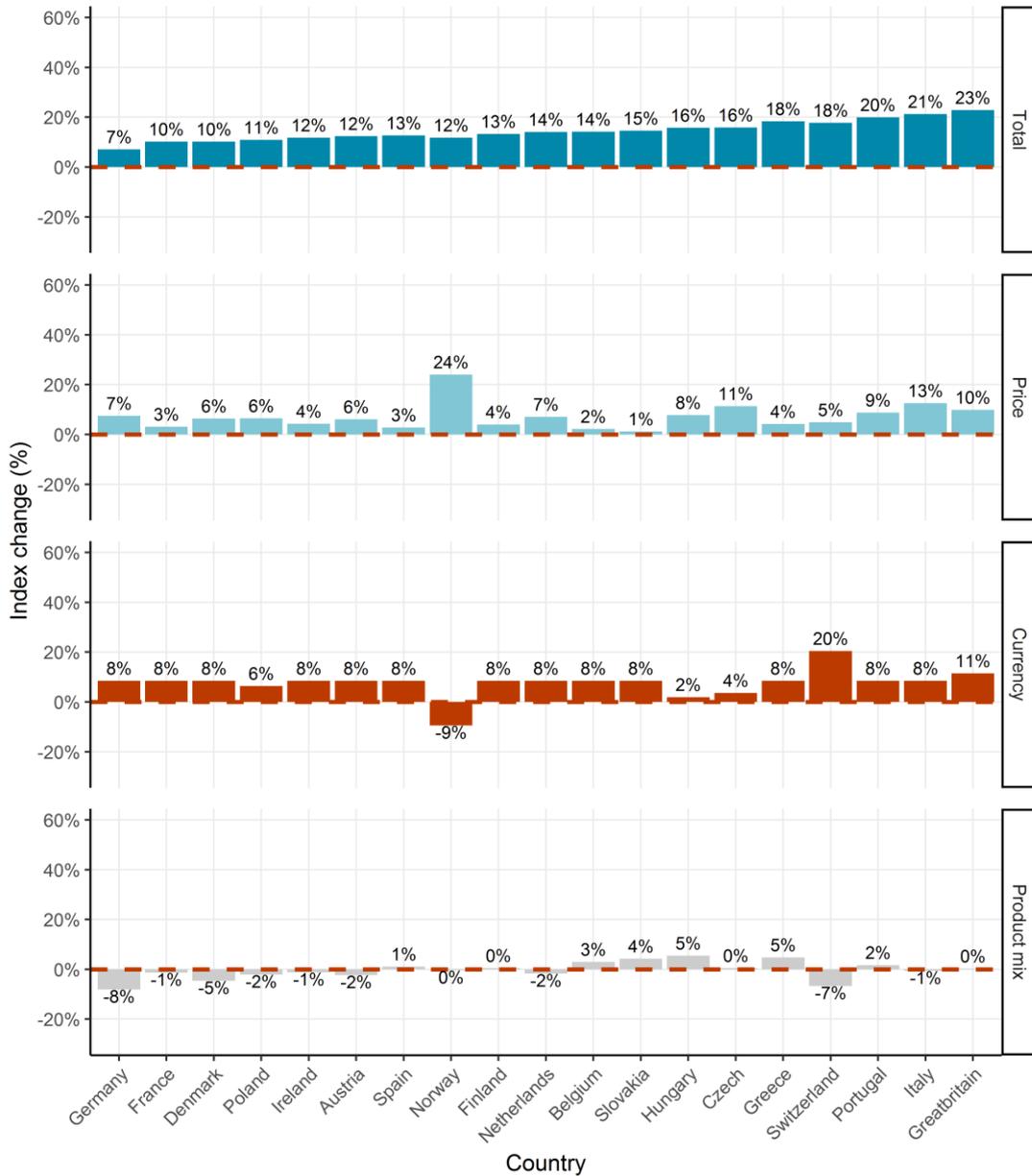
*Figure 12* shows the percentage change in the bilateral index per country between 2014 and 2018 divided into changes in price, currency and product mix. The top bar chart in the figure shows the total change in the index per country. Then the total change is shown divided into changes in price, currency and product mix (which both contain the effects of volume and product range in order to simplify the chart).

A positive percentage means that a country's index has risen in relation to Sweden (Sweden becomes relatively cheaper). For example, the figure shows that the index for the Netherlands rose by 14 per cent between 2014 and 2018. Of this change, seven percentage points can be explained by the fact that prices for pharmaceuticals in the local currency have increased relative to Sweden. At the same time, exchange rate movements between the euro and the Swedish krona have contributed eight percentage points. Changes in volume and product mix contributed to lowering the index for the Netherlands by around 2 percentage points.

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<sup>4</sup> The 15-year rule regularly reduces prices when a pharmaceutical reaches the age of 15 by 7.5 per cent.

Figure 12: Percentage change in a country's bilateral index in relation to Sweden between 2014 and 2018, broken down by changes in price, currency and product mix. Pharmaceuticals not exposed to competition.



Source: IQVIA and TLV analysis. Note: The effect of pharmaceuticals being discontinued in the market between 2014 and 2018 is not calculated. Therefore, the overall index change in the figure may differ slightly from the total change in other analyses.

The bilateral indices have increased for all countries between 2014 and 2018, which means that prices in other countries have increased in relation to Sweden. Price changes have consistently increased the index between 2014 and 2018, which means that the Swedish prices have fallen compared to other countries during the period. This price effect is generally slightly smaller than the currency effect.

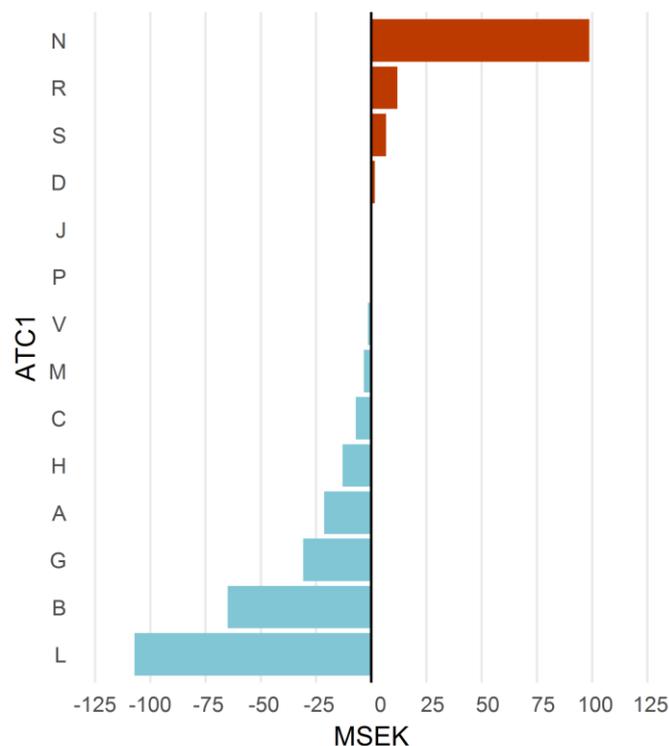
Currency fluctuations account for a significant share of the increase in all countries apart from Norway, where the currency has weakened against the Swedish krona and therefore contributes to dampen the change in index during the period.

Changes in the product mix have had mixed effects on the index and are difficult to interpret unambiguously. Compared with Germany, the prices of the pharmaceuticals that have increased in volume have become slightly cheaper in Germany compared to Sweden. However, this change takes place from a high level for the index in Germany. Above all, it can be noted that countries with an index higher than Sweden have a clearer negative change in the product mix. In addition to Germany, this also applies to Switzerland and Denmark.

*figure 13* illustrates the effect of differences in indices based on prices during the first quarter of 2018 and sales during the period April 2017 to March 2018. To show the differences for different groups of pharmaceuticals, the products have been grouped at ATC1 level, which is a way of describing the application area of a pharmaceutical.

*figure 13* shows that Sweden's cost for pharmaceuticals in the ATC group N (the nervous system) was around SEK 100 million higher during April 2017 to March 2018 due to Swedish prices being higher than the average in other countries. It was primarily the epilepsy pharmaceutical levetiracetam and the ADHD pharmaceutical methylphenidate which contributed to this cost difference (Table 3).

*Figure 13: Savings and additional costs at the ATC1 level as a result of price deviations from other countries, based on prices in Q1 2018 and volumes for rolling 12-month period through March 2018, 3-year average exchange rate,*



*Source: IQVIA and TLV analysis.*

Similarly, the cost of pharmaceuticals within the ATC group L (antineoplastic and immunomodulating agents) was around SEK 110 million lower than had been the case if the Swedish prices had remained at the same level as the average in other countries in the first quarter of 2018. It was mainly the TNF alpha inhibitor etanercept and the prostate cancer pharmaceutical enzalutamide (Xtandi) which contributed to this cost difference (table 3). This is shown by Table 3. Both substances are covered by collateral agreements between the county councils and the companies, which means that a certain part of the pharmaceutical cost is paid back to the county councils. There are likely agreements for these products in several other countries, which means that differences in prices and costs must be interpreted with some caution.

*Table 3: Savings and additional costs at substance level as a result of price deviations from other countries, based on volumes for rolling 12-month period through March 2018, 3-year average exchange rate, prices Q1 2018, pharmaceuticals not exposed to competition.*

ATC code	Substance	Difference in cost (SEK million)
N03AX14	Levetiracetam	38
N06BA04	Methylphenidate	32
L04AD02	Tacrolimus	18
L04AB06	Golimumab	14
A10AE04	insulin, glargine	14
A10BJ02	Liraglutide	13
N05AX13	paliperidone palmitate	13
N05AX08	Risperidone	11
L04AA06	Mycophenolate	-20
A10AC01	insulin, human, isophane	-20
B03XA02	darbepoetin alfa	-23
L02BB04	enzalutamide *	-24
A10AB05	insulin, aspart	-25
R03BA02	Budesonide	-28
N03AX12	Gabapentin	-39
L04AB01	etanercept *	-96

Source: IQVIA and TLV analysis.

\* There was a collateral agreement between companies and county councils during the period

*figure 14* shows how the differences in the bilateral price index are distributed between different ATC codes per country. With a few exceptions, countries with higher indices compared to Sweden have higher indices in all ATC codes. ATC code L (tumours and musculoskeletal disorders) explains a relatively large proportion of the index differences in countries where the index is high compared to Sweden. The other ATC codes account for approximately the same amount of the remaining difference. In countries with a low index and lower prices compared to Sweden, ATC code L and N explain a large part of the difference, with R (respiratory system) following.

Figure 14. The impact of various ATC-1 groups on the bilateral price index in the segment not exposed to competition, Q1 2018

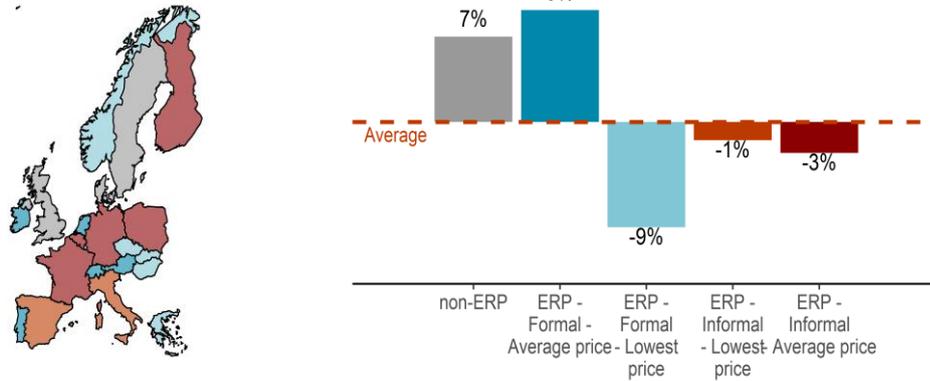
Total difference to Sweden	A	B	J	L	N	R	Other
Poland	-2%	-7%	0%	-6%	-5%	-5%	-2%
Greece	-2%	-1%	0%	-4%	-4%	-4%	-3%
Slovakia	-1%	-1%	0%	-6%	-3%	-2%	-2%
Hungary	-2%	-2%	0%	0%	-3%	-3%	-1%
Portugal	-1%	0%	0%	0%	-6%	-1%	-1%
France	-1%	0%	0%	-6%	-2%	-1%	0%
Czech	-1%	0%	-3%	-1%	1%	-2%	-1%
Spain	0%	0%	0%	-2%	-4%	0%	-1%
Belgium	-1%	2%	0%	-3%	-2%	-2%	0%
Finland	-1%	-1%	0%	-2%	-1%	-1%	0%
Norway	-1%	0%	0%	0%	-2%	-1%	-1%
Italy	0%	1%	0%	-1%	-1%	1%	2%
Austria	1%	1%	0%	-1%	1%	1%	1%
Netherlands	1%	4%	0%	2%	-2%	1%	2%
Denmark	2%	2%	0%	4%	0%	2%	2%
Greatbritain	2%	2%	2%	0%	2%	2%	7%
Ireland	2%	3%	0%	8%	2%	2%	3%
Germany	2%	1%	0%	13%	0%	1%	4%
Switzerland	3%	5%	0%	15%	3%	5%	3%

Source: IQVIA and TLV analysis.

### 3.2.5 Price index by different pricing models

Appendix 2: Pricing and reimbursement systems describes various pricing systems in the countries in question. One categorisation is between countries that apply international reference pricing and those that do not. Countries with international reference pricing can be divided into those that apply formal reference pricing and those that apply informal reference pricing. With a formal reference price, the price becomes binding. For informal reference price, the price is used as a basis for negotiation or in combination with other criteria. Furthermore, the pricing systems may differ in terms of whether the reference price is the average price in the basket or whether it reflects a minimum price. Figure 15: Prices of pharmaceuticals Q1 2018 not exposed to competition in relation to the average of the cross-sectional index, broken down by pricing system. describes how the index for different pricing systems relates to the average in the 20 countries.

Figure 15: Prices of pharmaceuticals Q1 2018 not exposed to competition in relation to the average of the cross-sectional index, broken down by pricing system.



Source: IQVIA and TLV analysis.

In the figure above, the red dotted line means that the prices are in line with the average of the prices for all countries in the comparison. Countries using *formal IRP – lowest price* have 9 per cent lower prices than average. The group *not IRP*, to which Sweden belongs, generally has higher prices. The figure also shows that the difference is small between having an informal/supporting reference pricing at the lowest prices or the same model at the average price. In *formal IRP* the difference is large depending on whether the prices refer to the lowest price or the average price.

### 3.3 Pharmaceuticals exposed to competition

Pharmaceuticals without patent protection and which are deemed to be substitutable on medical grounds usually face competition from generics. This section deals with differences in pharmaceutical prices for pharmaceuticals exposed to competition in Sweden and other European comparison countries. The countries in the comparison have different pricing and reimbursement systems in order to increase competition within substitutable pharmaceuticals and in Sweden the product-of-the-month system is used for this purpose. The product-of-the-month system, PV, gives the pharmaceutical with the lowest price, and which has been reported as available, temporary monopoly on sales at pharmacies over a period of one month.<sup>5</sup> The PV system constitutes just over 50 per cent of the volume but only 20 per cent of the cost for the Swedish pharmaceuticals. In the Swedish PV system, list prices are transparent and there are no further discounts, in contrast to the segment not exposed to competition. In other countries, there may be varying degrees of discounts that are not captured by the list prices. This constitutes an uncertainty as to which prices actually apply in different countries. Analyses of changes over time can be more robust if discounts move systematically over time. See more detailed description of the systems in the different countries in *Appendix 2*.

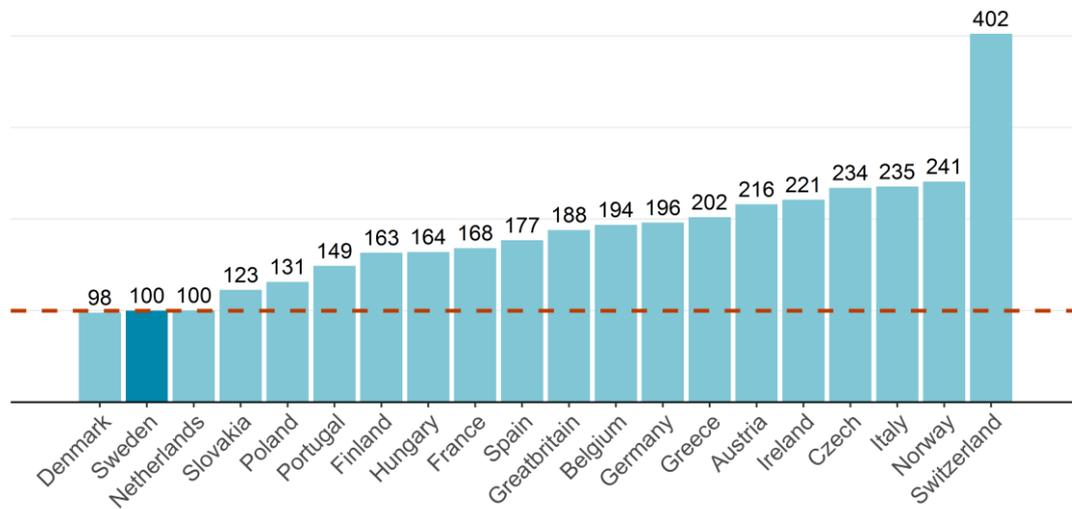
#### 3.3.1 Price index 2018

The countries in this report show significant differences in prices within pharmaceuticals exposed to competition. The price index varies more than in pharmaceuticals not exposed to competition, as reported in the previous section. *Figure 16* shows the 2018 index for pharmaceuticals exposed to competition. Index 100 means that pharmaceutical prices are in line with Sweden.

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<sup>5</sup> With the final sale of the previous month's PV and that prescribers, pharmacists and pharmacy customers on various conditions have the right to refuse substitution, the average market share for PV is about 70 per cent.

Figure 16. Bilateral price index, pharmaceuticals exposed to competition in 2018, Sweden = 100.



Source: IQVIA and TLV analysis.

The interpretation of the index is that Greece with an index of 202 has prices that are approximately twice as high as Sweden's prices for pharmaceuticals exposed to competition. In this segment, only Denmark has marginally lower prices than Sweden. Switzerland deviates significantly from other countries with prices that are approximately three times as high as Sweden's in Q1 2018.

In addition to other named uncertainties regarding the degree of matching and the occurrence of rebates/discounts, the price index in Norway and the Czech Republic in the figure above must be interpreted cautiously since the transaction price is not necessarily the same as the list prices used in this study. See the section *Nordic overview* for more information on how Norway's index changes when using transaction prices instead of list prices.

### 3.3.2 Degree of matching

The index figure above shows a bilateral index of prices within pharmaceuticals exposed to competition. Bilaterally means that the index compares all products available in both Sweden and a single comparison country. The proportion of Swedish medicines available in the comparison country is called the degree of matching and shows what proportion the Swedish products have been sold in a country. In Sweden, there are approximately 700 products in the sample for this segment, which is more than the segment not exposed to competition with only 200 products. There are often several products that compete within the same substance group within this segment. In the figure below, the degree of matching is divided into the pharmaceutical groups at ATC-1 level that have the largest sales within the PV system in Sweden. The pharmaceutical group A has the highest average degree of coverage among the countries, while group R has the lowest average. The country where the coverage is highest is Germany, where 77 per cent of the Swedish

products are available. Generally, the degree of coverage level is high for pharmaceuticals in the PV system.

*Figure 17: Degree of matching between Sweden and comparison countries 2018. Pharmaceuticals exposed to competition.*

	A	C	J	L	N	R	Other	Average
Sweden	100%	100%	100%	100%	100%	100%	100%	100%
Germany	87%	85%	75%	96%	74%	69%	71%	77%
Denmark	79%	75%	66%	64%	75%	50%	68%	72%
Finland	85%	76%	63%	84%	70%	64%	63%	71%
Netherlands	81%	75%	69%	44%	64%	64%	71%	68%
Greatbritain	81%	67%	61%	64%	67%	56%	75%	68%
Austria	79%	76%	68%	92%	66%	39%	60%	68%
Ireland	87%	76%	49%	92%	62%	58%	58%	66%
Switzerland	77%	68%	71%	96%	60%	56%	63%	65%
Norway	87%	73%	61%	16%	65%	75%	53%	65%
Spain	64%	70%	51%	52%	64%	67%	58%	63%
Belgium	60%	63%	68%	68%	55%	58%	57%	59%
Italy	70%	64%	53%	68%	54%	56%	58%	58%
Poland	57%	69%	58%	56%	50%	53%	66%	58%
Portugal	64%	63%	42%	48%	60%	56%	51%	58%
Czech	60%	66%	54%	80%	54%	42%	52%	57%
France	70%	60%	61%	68%	51%	64%	49%	56%
Hungary	62%	65%	59%	84%	51%	31%	53%	56%
Slovakia	57%	64%	54%	80%	49%	44%	51%	54%
Greece	64%	62%	41%	72%	50%	56%	51%	54%
Unweighted average	74%	71%	61%	71%	62%	58%	61%	65%

Source: IQVIA and TLV analysis.

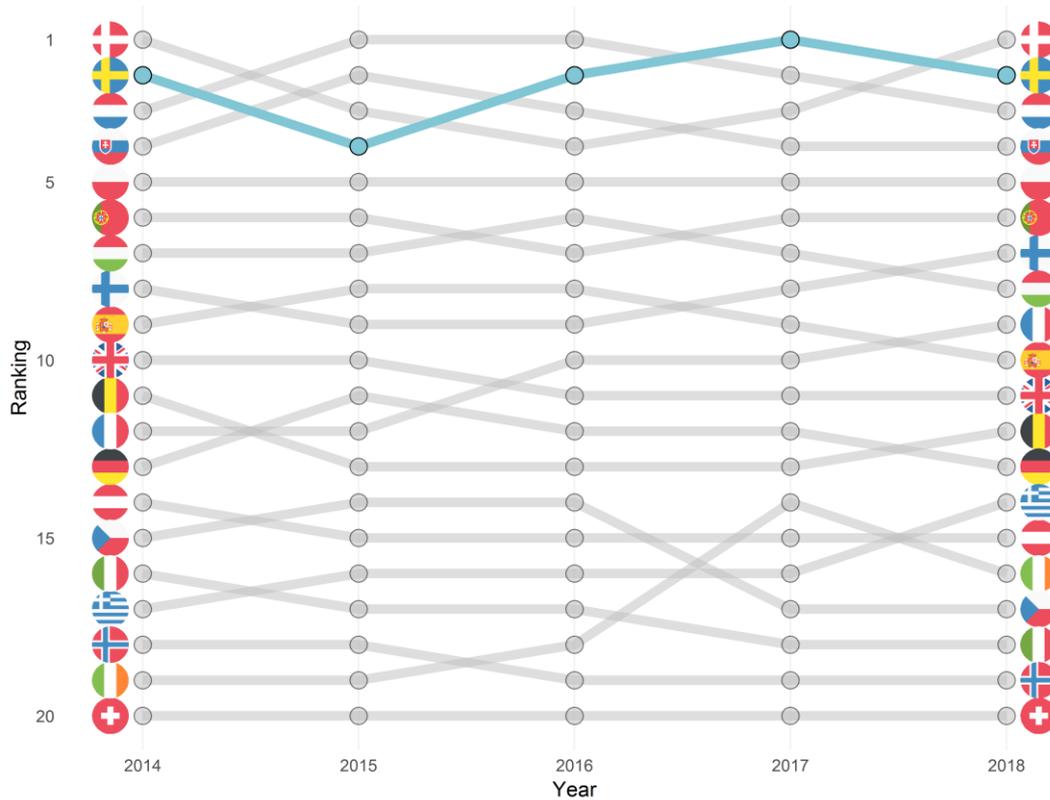
A high degree of matching and a pharmaceutical use that is similar to the Swedish situation means that the price comparison becomes more robust.

### 3.3.3 Historical development of pharmaceutical prices

Sweden's prices within pharmaceuticals exposed to competition have put Sweden amongst the four countries with the lowest prices during the years 2014 to 2018. During 2018, Sweden had the second lowest prices in the segment, which is the same as in 2014.

Figure 18 shows the ranking trend for each country in the comparison. Ranking position one means that the country has the lowest prices. Comparison countries that have changed rankings with Sweden during 2014 to 2018 are Denmark, Slovakia and the Netherlands. Two countries that have seen major price improvements in the years 2014 to 2018 are Ireland and France.

*Figure 18: Ranking of pharmaceutical prices in pharmaceuticals exposed to competition. All 20 countries. Sweden emphasised with blue line. The countries are marked with their respective flag. A position at the top of the figure means ranking position 1 and means lowest pharmaceutical prices.*

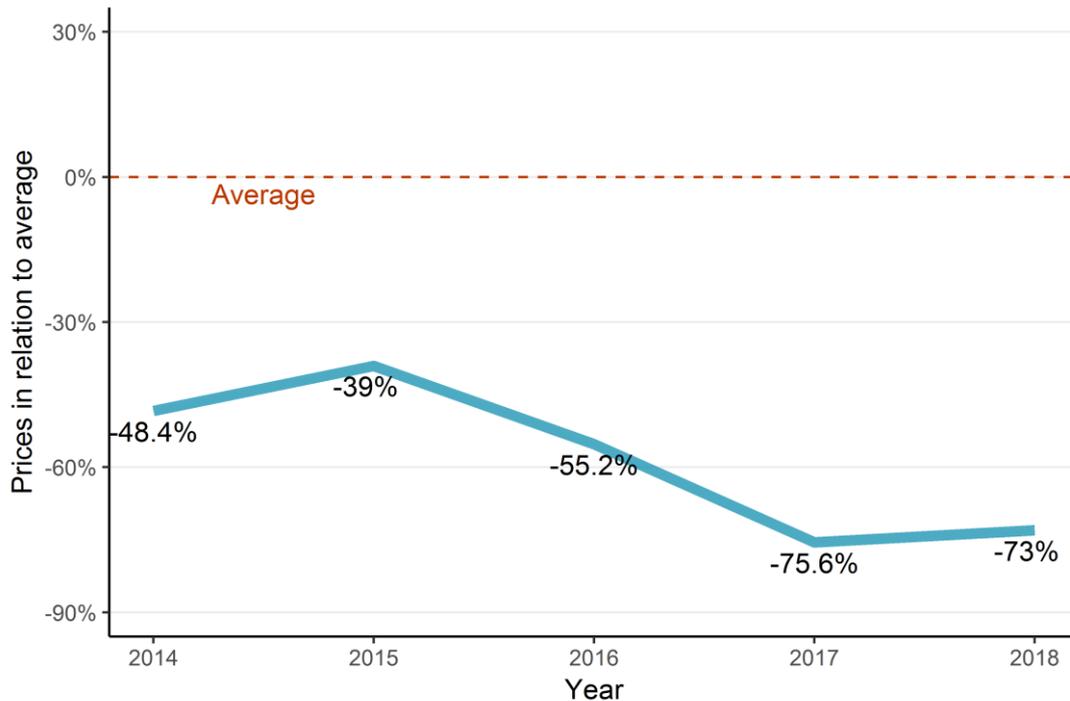


Source: IQVIA and TLV analysis.

The ranking over time,

*figure 18*, shows that Sweden continues to have amongst the lowest prices compared to other countries since 2014. However, it does not show how much the pharmaceutical prices have changed in relation to other countries. *figure 19* below shows how Sweden's prices in pharmaceuticals exposed to competition are in proportion to the average of all countries in the report.

Figure 19: Sweden's relative prices compared to an average of all countries per year, cross-sectional index, pharmaceuticals exposed to competition, exchange rate running average over 3 years.



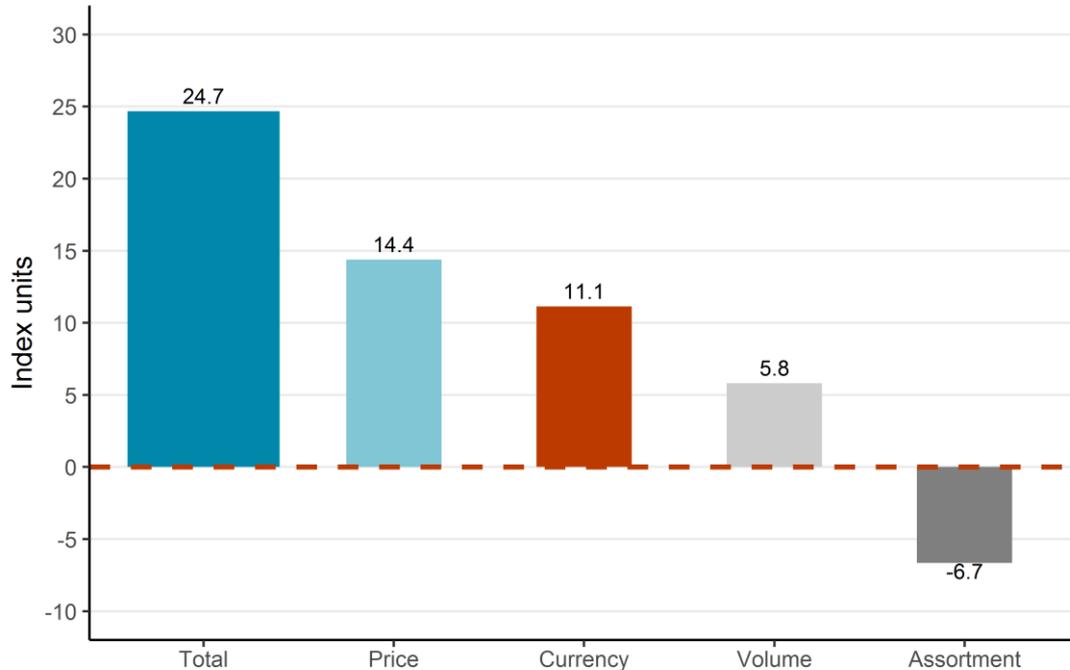
Source: IQVIA and TLV analysis.

The figure above should be interpreted as showing that in 2014, Sweden's prices for pharmaceuticals exposed to competition were 48.4 per cent lower than the average for the 20 countries included in this report. In 2018, Sweden's pharmaceutical prices have fallen to 73.0 per cent below the average, which is partly explained by lower prices and partly by a weaker Swedish krona. On average, the index has therefore increased by approximately 24.7 index units in relation to Sweden.

### 3.3.4 Drivers of the index

There are several factors that influence the comparison of pharmaceutical prices between countries. In this analysis, the development of the price index over time has been divided into changes in price, currency, volume and product range. The product mix effect is used when the product range effect and volume effect are combined. For a more detailed description of effects, see description to *Figure 12* or *Methodology in Appendix 1* for more details.

Figure 20: The number of index units that the cross-sectional index has changed by between Q1 2014 - Q1 2018. The total is divided into price effect, currency effect, volume effect and product range effect. Pharmaceuticals exposed to competition.

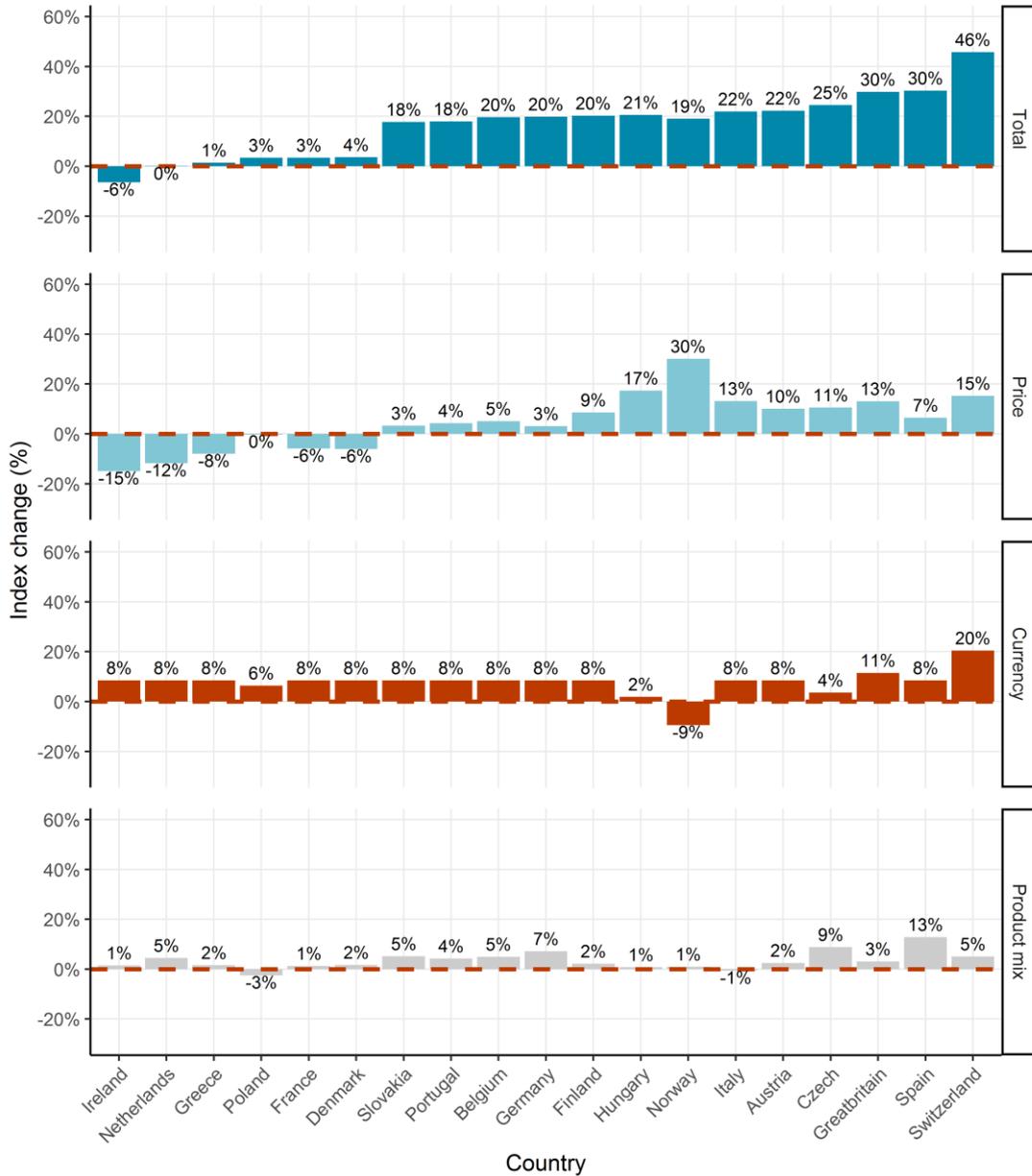


Source: IQVIA and TLV analysis.

Figure 20 shows what drives the development of the index between 2014 and 2018. The total change between 2014 and 2018 is equivalent to an increase in the average of the indices of all countries, calculated as the cross-sectional index, with approximately 24.7 index units. An increase means that Sweden has become relatively cheaper. The price effect constitutes most of the change with 14.4 index units. This effect accounts for how much the prices in other countries have changed and therefore gained a higher index on average. This is a result of changed list prices in Sweden or abroad, all other things being equal. Currency fluctuations contribute approximately a further 11.1 index units. Sweden has benefited from the weaker krona. Changes due to volume and product range move in different directions and, on the whole, essentially cancel out one another.

Figure 21 shows how the bilateral index has changed as a percentage for all countries in the report. At the top are the total change and then price effects, currency effects and product mix effects. Changes in volume and product range have been merged in order to simplify the figure. Note that bilateral indices differ from cross-sections in the figure above, the results differ.

Figure 21: Percentage change in bilateral index between 2014 and 2018, broken down by price effect, currency effect, and product mix effect per country. Pharmaceuticals exposed to competition.



Source: IQVIA and TLV analysis. Note: The effect of pharmaceuticals discontinued from the market between 2014 and 2018 is not calculated. The overall index change in the figure may therefore differ slightly from the total change in other analyses.

The figure should be interpreted as showing that between 2014 and 2018, Ireland had 6 per cent lower index units in the segment exposed to competition compared to Sweden, which by definition has an index of 100. This means that Ireland, which has higher prices than Sweden, approached Swedish prices between 2014 and 2018. However, the underlying effects have previously moved in different directions. For

Ireland, currency fluctuations have had an upward effect on the index of 8 percentage points, since the euro has become stronger in relation to the Swedish krona. However, Ireland has experienced lower pharmaceutical prices in euros equivalent to 15 percentage points. The remaining difference is shown in the product mix effect and is due to new pharmaceuticals being added and that Sweden's volume distribution of pharmaceuticals changed during the period. In summary, Ireland's index level has fallen in comparison with Sweden by 6 per cent in pharmaceuticals exposed to competition. In recent years, Ireland has changed its basket of comparison countries in its pricing, which seems to have had a price-pressing effect.

### 3.3.5 Pharmaceutical prices in different substances

At substance level, there are pharmaceuticals where prices are higher than average. In particular two substances differ. The substance pregabalin, used to treat epilepsy, has a higher price in Sweden than the average. If Sweden had an average price in line with other countries, the pharmaceutical costs would be reduced by SEK 81 million. The second substance in which Sweden has a higher price is methylphenidate, which is an ADHD pharmaceutical.

*Table 4: Savings and additional costs at substance level as a result of price deviations from other countries, based on volumes rolling 12 months through March 2018, 3-year average exchange rate, prices Q1 2018, pharmaceuticals exposed to competition.*

<b>ATC code</b>	<b>Substance</b>	<b>Difference in cost (MSEK)</b>
N03AX16	pregabalin	81
N06BA04	methylphenidate	65
N07CA01	betahistine	7
N06AX12	bupropion	7
S01ED51	travoprost, timolol	5
A07AA02	Nystatin	4
S01EC04	Brinzolamide	3
H02AB06	Prednisolone	3
L02BB03	Bicalutamide	-81
C09CA06	Candesartan	-82
C09CA01	Losartan	-100
C08CA01	Amlodipine	-100
C10AA01	Simvastatin	-121
N06AB06	Sertraline	-122
A02BC01	Omeprazole	-149
C10AA05	Atorvastatin	-212

Source: IQVIA and TLV analysis.

There are several substances whose prices in Sweden are significantly lower than the average in other countries.

*Table 4* shows that if Sweden had average prices for atorvastatin, omeprazole and sertraline, the cost would increase by about half a billion kronor.

Once again, these prices illustrate differences in list prices between countries. For Sweden, these prices are transparent and are the prices that apply. This also applies, for example, to Denmark. But several other countries have hidden discounts in pharmaceuticals exposed to competition, which may overestimate price differences with other countries.

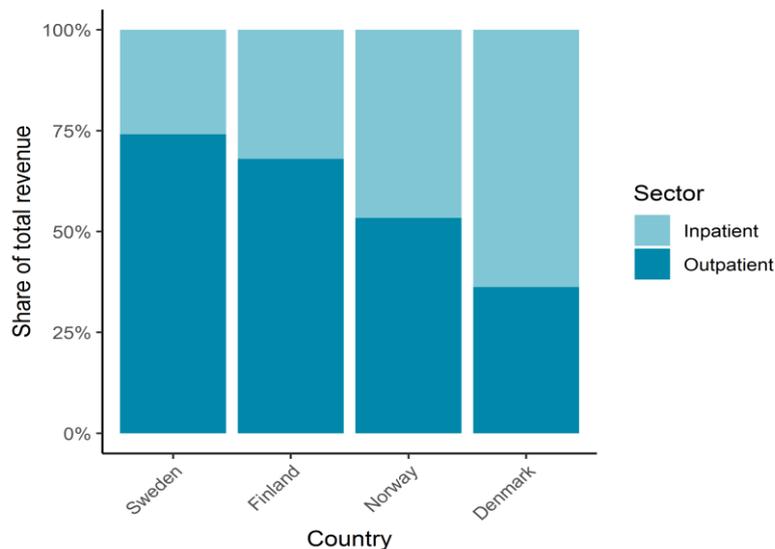
## 4 Nordic overview

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In this section, the prices of pharmaceuticals in Sweden, Norway, Denmark and Finland are analysed. There are significant differences between these countries in the management of the pharmaceuticals included in the sample. *Figure 22* shows how the use in each country is divided between outpatient and inpatient care for medicines not exposed to competition. Sweden has large sales in outpatient care, unlike Denmark for example, where more than half of sales are in inpatient care.

The differences in the management of pharmaceuticals mean that a comparison based on the assumption that a pharmaceutical should be used in outpatient care in both countries will become more uncertain. Thus, in order to maximise the number of pharmaceuticals that can be included in the comparison, prices in inpatient care are used in the comparison countries when these prices are available, and the pharmaceutical is used in inpatient care. In this way, the number of pharmaceuticals that match increases, and the analysis become more robust.

*Figure 22: Distribution between outpatient and inpatient care of the total sales value of pharmaceuticals not exposed to competition, sales AIP running 12 months through March 2018.*

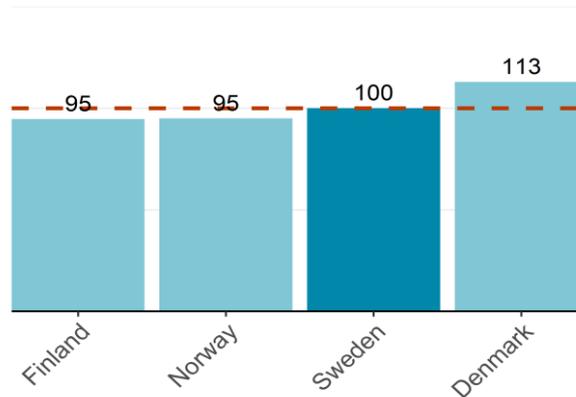


Source: IQVIA and TLV analysis.

### 4.1.1 Medicines not exposed to competition

If the sample is limited to medicines used in outpatient care in both Sweden and each respective country, Finland has the lowest price index and Sweden is ranked in position 3 out of 4 (see *Figure 23*).

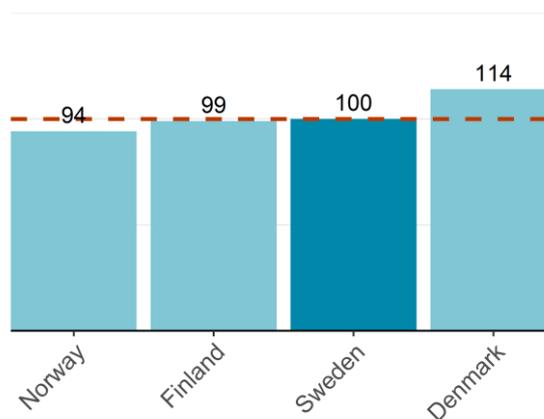
Figure 23: Bilateral price index for pharmaceuticals not exposed to competition in outpatient care, Q1 2018, volumes running 12 months up to and including March 2018.



Source: IQVIA and TLV analysis.

If pharmaceuticals used in outpatient care in Sweden but which are managed in inpatient care in other neighbouring countries are also included, the degree of matching increases and the index changes slightly. For example, the degree of matching against Denmark increases from 47 per cent to 64 per cent. This is because products that have high sales in outpatient care in Sweden are mostly used in inpatient care in Denmark. Examples of such products are the TNF alpha inhibitors adalimumab and etanercept. Against Finland, the degree of matching increases from 56 per cent to 60 per cent and against Norway from 51 per cent to 62 per cent. By taking into account sales that take place in inpatient care in the comparison countries, the degree of matching rate increases and the comparison becomes more reliable.

Figure 24: Bilateral price index for pharmaceuticals without competition in outpatient care and inpatient care, Q1 2018, volumes continuously 12 months up to and including March 2018.



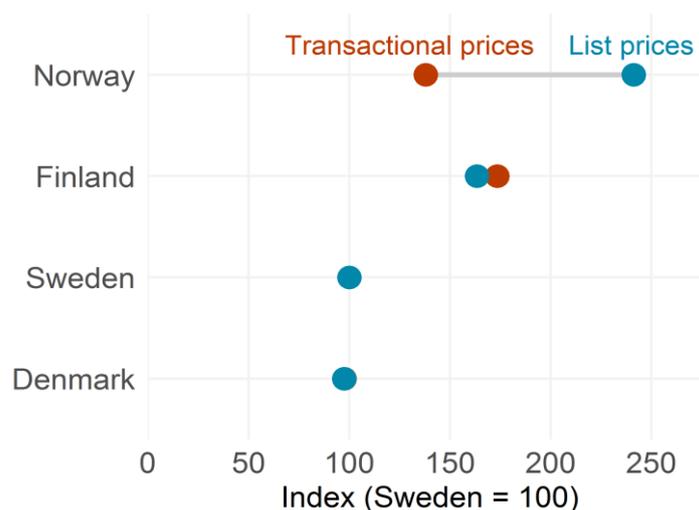
Source: IQVIA and TLV analysis.

For medicines not exposed to competition, all Nordic countries use different types of risk-sharing models that reduce the cost of pharmaceuticals compared to list prices. In Sweden, the total rebate amounted to around SEK 2.2 billion on a continuous basis for 12 months until March 2018. In addition to discounts on pharmaceuticals that are used in outpatient care in Sweden but in inpatient care in the Nordic neighbouring countries, Norway's and Denmark's discounts consist of pharmaceuticals also used by Sweden in inpatient care. The major sellers in inpatient care are not included in the selection of pharmaceuticals made in this analysis. Data on discounts in other countries can therefore not be easily converted to effects on the index.

#### 4.1.2 Pharmaceuticals exposed to competition

IQVIA not only provides list prices but also data on “estimated transaction prices”.<sup>6</sup> In a Nordic comparison of prices for pharmaceuticals exposed to competition, it may be relevant to use these alternative prices. One reason is that list prices for pharmaceuticals exposed to competition in Norway can be considered as maximum prices that do not fully reflect the actual prices for which pharmaceuticals are sold. *Figure 25* also shows the differences in the index between the Nordic countries when estimated transaction prices are used instead of list prices. In this analysis, no merger of outpatient and inpatient care is made because pharmaceuticals exposed to competition are primarily managed in outpatient care in the Nordic countries.

*Figure 25: Bilateral price index for pharmaceuticals exposed to competition based on list prices and estimated transaction prices respectively*



Source: IQVIA and TLV analysis.

If the comparison is based on list prices, Norway has the highest prices of the Nordic countries. However, there is a significant change in the index if the

<sup>6</sup> Of the two data sets, "list prices" are more complete. "Estimated transaction prices" may be useful when list prices are unavailable or cannot be used for other reasons.

comparison is based on estimated transaction prices instead. Then Norway falls by over 100 index units from 241 to 138, with an index that is lower than Finland. Finland's index increases marginally in relation to Swedish prices. This is because Sweden's index falls more in relation to Finland's index when estimated transaction prices are used instead of list prices.

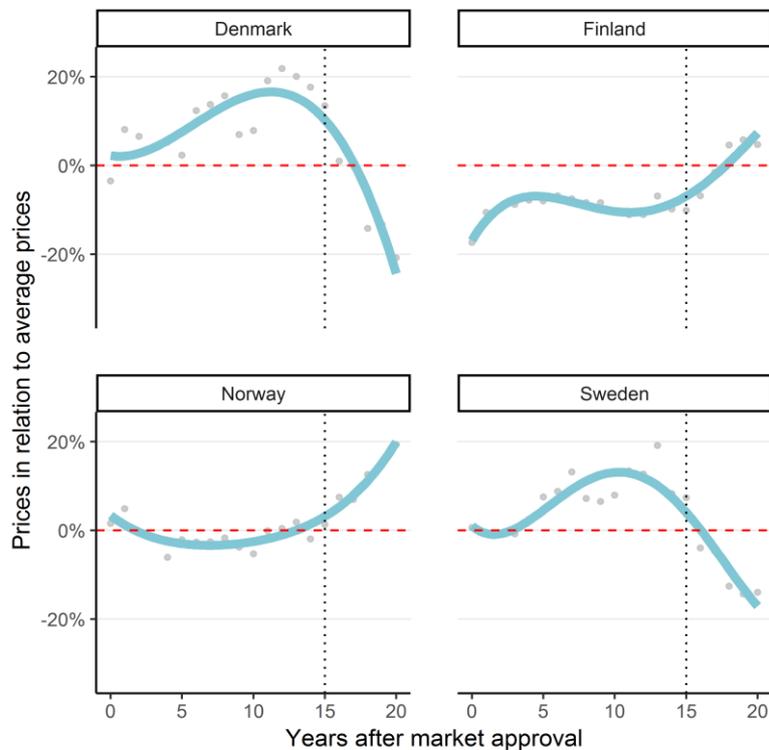
#### 4.1.3 Prices in Nordic countries by age of pharmaceuticals

An interesting aspect is the price dynamics over the life cycle of a pharmaceutical. However, in the data set, access to price changes is limited to the period 2014 to 2018, which is a short period in the context. It is therefore not possible to follow a pharmaceutical's relative price development over a long period of time.

*figure 26* shows the average prices in the countries for pharmaceuticals in relation to other countries according to the age of the pharmaceuticals from European market approval. In order to manage the fact that list prices in Norway often deviate from the actual transaction prices of pharmaceuticals exposed to competition, transaction prices are used throughout in the calculation.

The figure shows that Swedish prices are on par with the average for the first five years from market approval. Between year five and 15, Swedish prices are higher than average. After year 15, Swedish prices fall to a level below average among the countries.

*Figure 26 Relative pharmaceutical prices in the Nordic countries compared to the average price for the report's 20 European countries, per year after market approval. Outpatient care.*



Source: IQVIA and TLV analysis.

Among the Nordic countries, Denmark exhibits a price dynamic over the life cycle that is similar to Sweden's. Norway exhibits a reverse pattern with prices that are lower than Sweden and Denmark for earlier age groupings, but where prices rise in relative terms when the pharmaceutical approaches fifteen years old. Finland is interesting since the country exhibits declining relative prices for pharmaceuticals with an age of five to 15 years, which is the age range where Sweden's prices increase in relation to the average in Europe.

## 5 Discussion

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One factor that affects the comparison of prices between countries is exchange rates. The Swedish krona has fallen in value against the euro in recent years. Since prices for pharmaceuticals in Sweden are set in Swedish kronor, Swedish prices appear to be lower when the currency falls in value. In order to accommodate this, an average exchange rate over three years is used in this report. This means that Sweden's relative prices are not fully affected by the weak exchange rate that applied during the first quarter of 2018.

In the pharmaceutical segment not exposed to competition, Sweden has approximately the same number of countries with lower as with higher prices, and Sweden is ranked in position 12 out of 20 countries. Nordic countries such as Norway and Finland have lower prices than Sweden in this segment.

Since 2014, Sweden's price index has fallen in relation to other countries. From Sweden's price index being around 8.6 per cent above average in 2014, Sweden's prices are around one per cent below the average in 2018. Prices in other countries have risen in relation to Sweden. Since 2014, Sweden's relative prices have fallen in relation to other countries within pharmaceuticals not exposed to competition. From Sweden's prices being around 9 per cent above average in 2014, Sweden's prices were around one per cent below average in 2018. Prices in other countries have risen in relation to Sweden. The weak Swedish currency has not led to an increase over time in the established list prices for pharmaceuticals not exposed to competition in Sweden. In Norway, prices have increased partly as a result of a weaker currency.

Of this change, about sixty per cent can be attributed to currency fluctuations (a weaker krona) and forty per cent to changes in prices. The weak Swedish currency has not led to an increase over time in the established prices for pharmaceuticals not exposed to competition in Sweden, the Swedish value-based system appears to have been robust from this point of view. But the longer the Swedish currency remains weak, the greater the pressure can be to increase list prices or prices for new pharmaceuticals. In Norway, the weaker currency has instead resulted in increased prices, as a result of the Norwegian system.

A comparison of prices within different pharmaceutical groups not exposed to competition at the ATC1 level shows that Sweden has higher prices than the average for pharmaceuticals within the ATC1 group N (nervous system) and lower prices for pharmaceuticals within the ATC1 group L (antineoplastic and immunomodulating agents). This result should be interpreted with caution as pharmaceuticals in some ATC1 groups are widely used in inpatient care in other countries. This applies in particular to ATC1 group L, where many other countries as well as Sweden have hidden rebate levels for TNF alpha inhibitors, for example, or risk sharing systems for new expensive cancer treatments.

For medicines exposed to competition, included in the PV system, Sweden has the lowest prices in the comparison, together with Denmark and the Netherlands. These countries have created systems that steer towards the cheapest option of substitutable pharmaceuticals. In Sweden, this has contributed to the PV system constituting just over 60 per cent of the sales volume, but only one fifth of the sales value.

In this report, price dynamics over the age of a pharmaceutical have been analysed for the years 2014 up to and including 2018. The prices of new pharmaceuticals in Sweden are in line with other countries at launch. However, during the period when pharmaceuticals are between 5 and 15 years old, Sweden's prices are higher than the average. The reason for this development is that the prices fall in other countries but not in Sweden. For pharmaceuticals that are 15 years and older, the index is significantly lower than the average. The reason is the PV system's low prices. For pharmaceuticals that are not considered substitutable and thus not included in the PV system, prices will only fall to the average after 15 years. The 15-year rule is an important tool for reducing the prices of these pharmaceuticals.

The majority of the countries in the comparison have some form of international reference pricing. The pricing system that shows lowest prices within pharmaceuticals is formal reference pricing with the lowest price as a reference, which is applied by Norway, among others. TLV will continue to follow pharmaceutical prices from an international perspective. One priority area is the life cycle of pharmaceuticals and the dynamics of the pricing system over time. A further ambition is to conduct analyses that are more in-depth of the time it takes for new pharmaceuticals to be launched in Sweden from market approval within the EU, and how it affects the launch price. Since countries in Europe, as in Sweden, increasingly have different types of discounts or risk sharing systems for pharmaceuticals not exposed to competition, an ambition is to be able to also capture these aspects, at least at a macro level. It is rarely possible to break down these agreed prices on individual pharmaceuticals or even pharmaceutical groups.

# Appendix 1: Sensitivity analysis and methodology

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## Sensitivity analyses

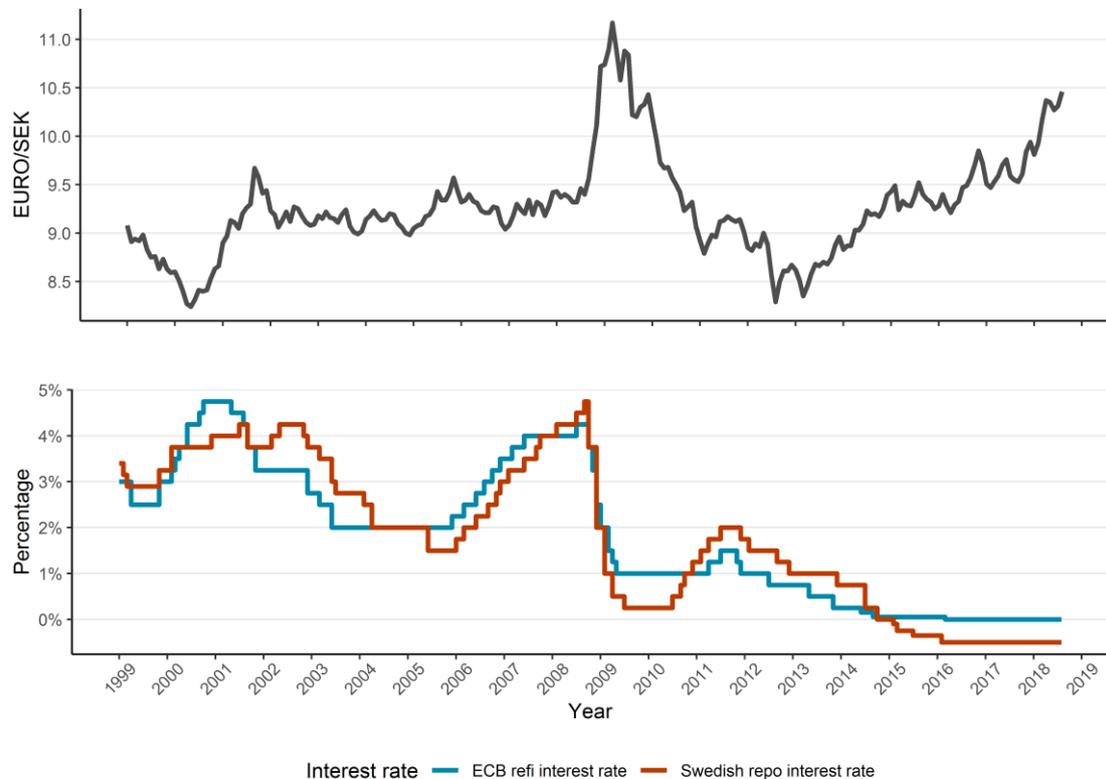
### Exchange rate

One factor that affects prices over time is the exchange rate. Currency fluctuations affect relative prices compared to other countries. If the currency strengthens in one country, prices in other countries appear to have decreased, even though they are nominally unchanged in each country's respective currency. A weaker Swedish krona, all other things being equal, means that Swedish prices appear to be lower than if the krona were strong.

The significance of the exchange rate for relative prices has become additionally important in this year's report, because the Swedish krona is currently weaker than it has been for a long time. During the first quarter of 2018, the krona weakened against the dollar and the euro. An important explanation is that the Riksbank in Sweden is one of the central banks that lowered the interest rate the most and the tender (repo) interest rate has been negative since February 2015.

The fluctuations in the exchange rate depend on many factors, where expectations play a major role. According to accepted theory, the exchange rate in the long term should primarily reflect differences in (expected) price levels between countries. However, in the short term the exchange rate is primarily governed by differences in interest rates between countries. The figure below illustrates how the krona has fluctuated in relation to the euro, and also how the interest rate gap in policy rates between Sweden and the EMU has fluctuated.

Figure 27 Exchange rate krona/euro and the Riksbank's repo rate and the ECB's refi-rate, 1999-2018.



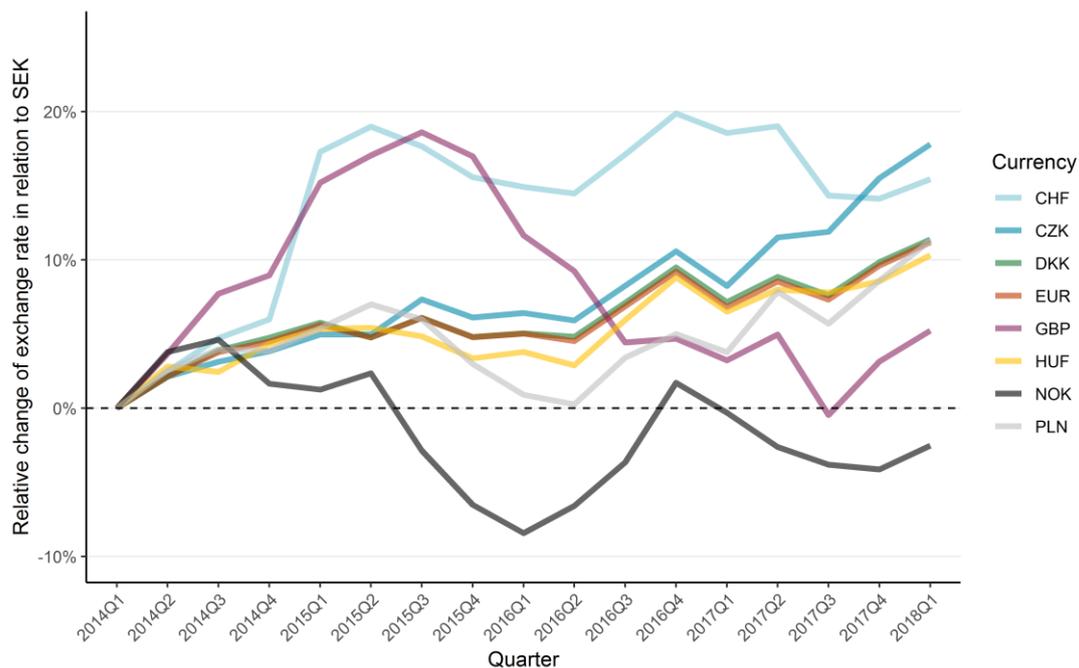
Source: SCB.

Sweden had a relatively stable exchange rate against the euro of around SEK 9 per euro during the early 2000s. In connection with the global financial crisis 2008/2009, and the turbulence that arose, the Swedish krona fell when international capital fled to safer/larger currencies. Subsequently, there was a period when Sweden had higher interest rates than the EMU countries (2011-2014). The euro fell during the first half of this period, to levels down to 8.50. However, the Riksbank continued to lower its interest rates to levels below the level held by the ECB. In connection with this, the krona weakened further. For almost three years, Sweden has had a negative policy rate. The exchange rate has risen during the period and in August 2018 it was SEK 10.50 per euro.

It is reasonable to believe that the Riksbank will not maintain an interest rate level in the long term that is clearly below the interest rate that applies in the EMU area. In the long term, the exchange rate will be determined by fundamental forces such as relative growth and inflation. Given that inflation and growth in Sweden are similar to that in the EMU area, the exchange rate can be expected to return to more normal levels when the Swedish interest rate is adapted to the rate in the rest of the EU. In that case, a benchmark can be the historical level of just over SEK 9 per euro.

In the light of the fact that the krona is currently historically weak, and that this is mainly due to the interest rate policy pursued, three-year ongoing average exchange rates are used throughout. The exchange rate against the euro will then be SEK 9.5 per euro for 2018, which is more in line with historical levels. In this way, a more accurate picture is obtained of how differences in prices reflect fundamental causes rather than the weak exchange rate. This also applies to index data reported for other years. The only exception is in the sensitivity analysis in order to illustrate the effect of a non-constant exchange rate.

Figure 28: Relative exchange rate fluctuation of the currencies of the report's countries in relation to the Swedish krona. Q1 2014 - Q1 2018.



Source: Eurostat and TLV analysis.

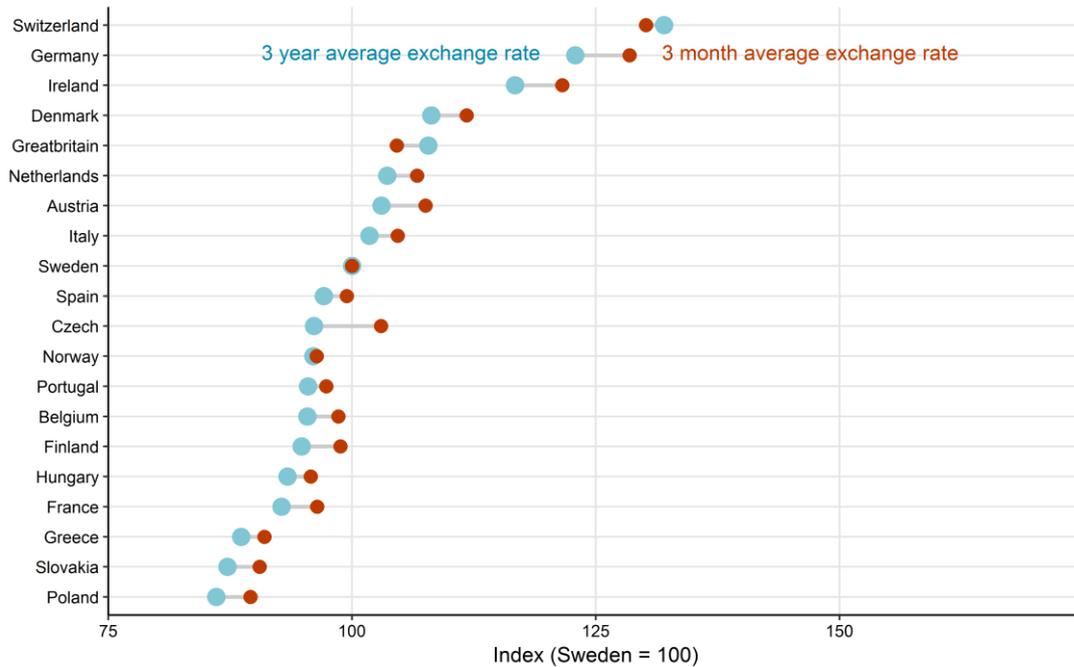
The figure above illustrates the relative exchange rate fluctuation for the Swedish krona for the period 2014 - 2018. The period has occasionally been characterised by large movements in the foreign exchange market. Most currencies strengthened against the Swedish krona from 2014 to 2015. They have then remained at a higher level and have also risen slightly. The exception is the British pound that has fallen back. The only currency that has lost value in relation to the Swedish krona during 2014-2018 is the Norwegian krona.

#### *More stable results with rolling average for currency adjustments*

In TLV's previous price comparison reports, exchange rates based on the average exchange rate for the last year's Q1 (January-March) have been used. Since currencies can fluctuate between years, this can have a major impact on the index for individual years. Instead, rolling averages for the last three years have been used

in this report. Below, the reader can see a comparison between the two alternatives for the 2018 index.

*Figure 29: Bilateral index 2018 when using a 3-year average exchange rate (blue) and a 3-month average exchange rate (red). Pharmaceuticals not exposed to competition.*



Source: IQVIA and TLV analysis.

The figure above should be interpreted in such a way that the blue dots are the index shown in the results section on pharmaceuticals exposed to competition, see *Figure 16*. Red dot describes how the index would change if the average of exchange rates for three months was used instead of three years. Since the Swedish krona has fallen in value against other currencies, the comparison countries would appear to have higher prices if a 3-month average exchange rate was used. For example, the Czech Republic goes from an index value that is below the Swedish index of 100, to being over.

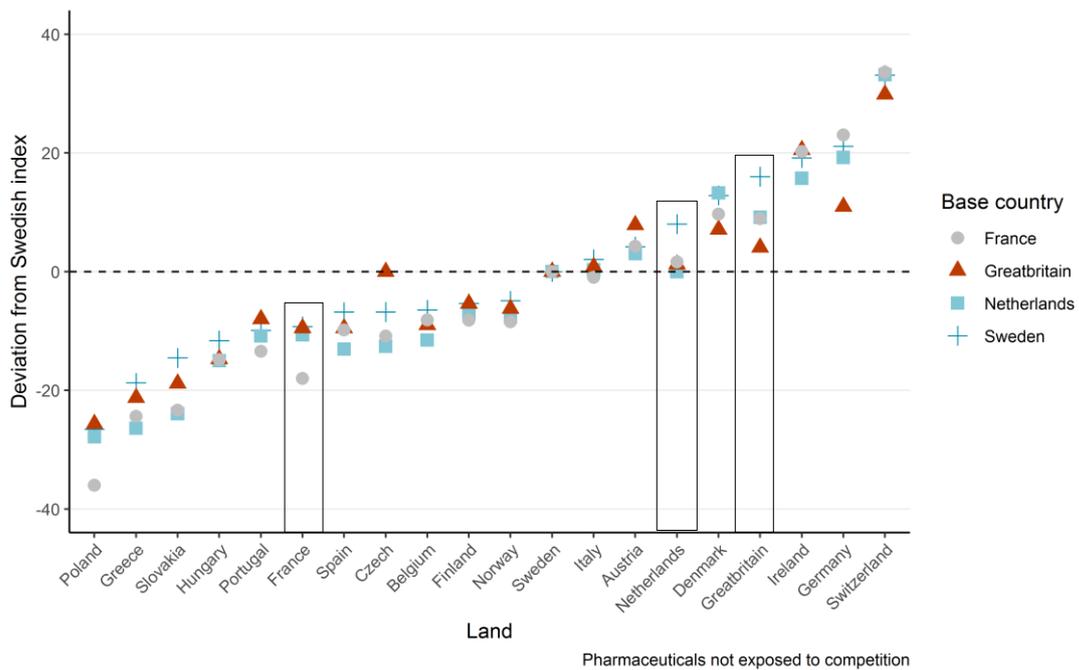
#### Effects on index of changing base country

Throughout this report, Swedish volumes have been used for the weighting of price baskets. The country whose volumes are used for weighting tends to strengthen their position in relation to other countries. For further discussion about this, please see, for example, Brekke and Holmås (2012) and TLV's previous price comparison reports.

The reason why the country whose sales volumes are used as the base weight tends to have a better outcome is the connection between use and price. If a pharmaceutical is cheaper, the use of the product often tends to be high.

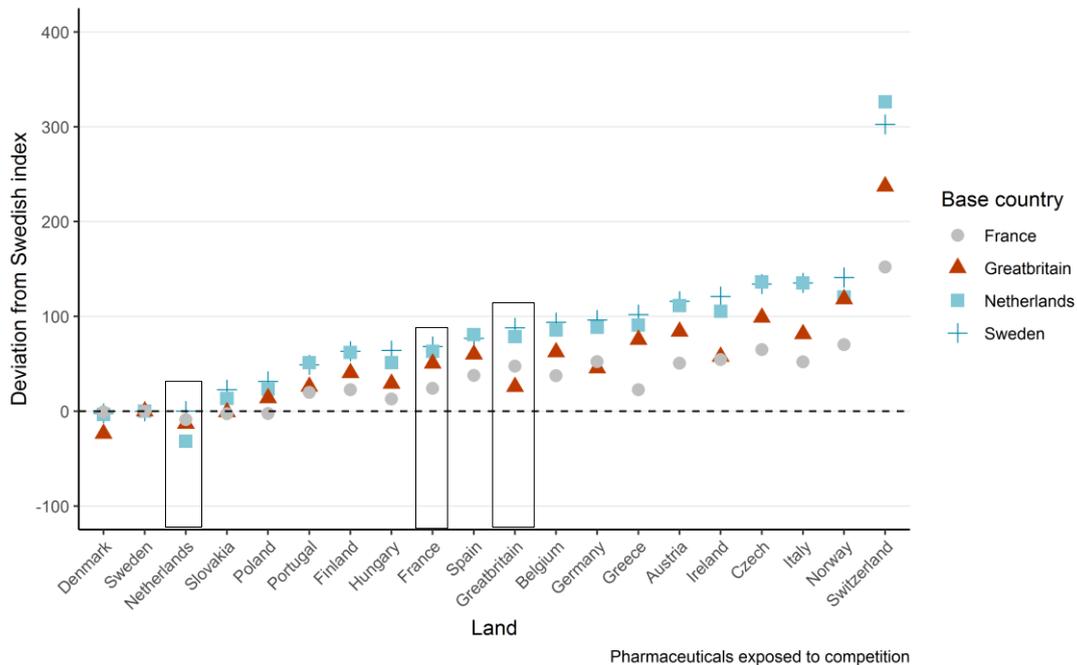
In this section, the base country will be changed from Sweden to France, the Netherlands and the UK. These countries were chosen because they are part of different pricing categories for pharmaceuticals not exposed to competition. The UK applies indirect price control, the Netherlands formal reference pricing, and France informal/supporting reference pricing. The countries also differ in terms of pricing for the other segment exposed to competition, where the Netherlands show the largest similarity with the product-of-the-month system in Sweden.

Figure 30: Change of base country for bilateral index. Pharmaceuticals not exposed to competition, 2018.



Source: IQVIA and TLV analysis.

Figure 31: Change of base country for bilateral index. Pharmaceuticals exposed to competition, 2018.



Source: IQVIA and TLV analysis.

Selection of base country for bilateral indices affects the levels and ranking order between the comparison countries. The deviation from the index per segment can be found in the figures above. For example, if France were to be used as a base country, the index of pharmaceuticals exposed to competition would be lower for almost all countries in comparison with Sweden. This means that Sweden's results benefit from this report being based on Sweden's pharmaceuticals. Countries tend to have lower prices for pharmaceuticals that they use a lot. A similar trend can be observed in the segment not exposed to competition.

## Methodology

### 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 with generics are considered to be exposed to competition. These segments are:

- Pharmaceuticals not exposed to competition (outside the product-of-the-month system)
- Pharmaceuticals exposed to competition (within the product-of-the-month system)

The segment for pharmaceuticals not exposed to competition includes products where there has been no competition between at least two different substitutable pharmaceuticals in Sweden. The segment includes both products that are patented and products whose patent protection has expired, but where competition between two substitutable pharmaceuticals has not occurred. As a rule, biosimilars are also included in this segment since 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 originator pharmaceutical products and that the conditions for the price formation then become the same as for originator pharmaceutical products. However, the competitive conditions may differ between the countries in the comparison. The segment for pharmaceuticals exposed to competition (within the product-of-the-month system) includes all pharmaceuticals that were included in the generic substitution within the product-of-the-month system in March 2018.

#### Data set and selection of pharmaceuticals

The starting point of the analysis is the highest-selling prescription pharmaceuticals in Sweden that are part of the pharmaceutical benefits scheme.

Prior to TLV's first report in 2014, IQVIA<sup>7</sup> was commissioned to provide data for 200 substances within the “protected pharmaceuticals” segment, 180 substances within the segment “unprotected original pharmaceuticals not exposed to competition” and 200 substances within the segment “unprotected pharmaceuticals exposed to competition” with the most sales. Each year thereafter, the data material was updated and expanded with new pharmaceuticals that demonstrated high sales. In this year's report, the sample contains 243 substances in the segment “protected original”, 210 substances in the segment “unprotected pharmaceutical not exposed to competition”, and 299 substances with (generic) competition.

Price indices reported in this study are based on list prices and on the pharmacy purchase price (AIP) or equivalent. AIP is used as a price measure because it does not contain pharmacy trade margins, which can vary between countries depending on how compensation to pharmacies is handled in each country.

#### Pharmaceutical matching method

This price comparison analyses weighted prices for different “price baskets” of pharmaceuticals. What is defined as a product can be interpreted differently. Pharmaceutical matching can be performed in different ways, with different consequences for precision and in how many countries a pharmaceutical is included in the comparison.

In this analysis, a product is defined as a pharmaceutical with the same substance, dosage form and strength. The definition does not include pack size, since the choice of pack size used differs depending on the country.

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<sup>7</sup> IQVIA was named IMS Health before November 2017.

In Sweden, medicines are normally dispensed by pharmacies for a three-month period, while a one-month period is the norm in Southern Europe. Thus, larger pack sizes are sold in Sweden compared to countries in which prescriptions are filled at shorter intervals. If the pack sizes that are usually sold have a lower price than those with lower sales volumes, it would mean that large pack sizes would be given greater weight and would thus benefit Sweden in a price index. To correct for this, the price has been calculated as cost per unit for a particular substance, dosage form and strength. This makes it possible to compare different pack sizes with each other, making the price indices more accurate. This practice increases the degree of matching with other countries, although the precision of the comparison is somewhat poorer than when matching at the pack level.

An alternative would be matching at the pack level, which means that exactly the same pack in terms of substance, dosage form, strength and size must be available in both Sweden and the comparison country in order to be included. This method has a high degree of precision, as the pharmaceuticals are consistent in terms of packaging. At the same time, there is a greater risk that a specific pack will not be available in very many countries. Pack size often correlates to dispensing frequency. The longer the time between dispensing, the greater the probability that larger pack sizes are more common, and vice versa.

Another option would be to measure the costs incurred by each country for a specific therapy group, regardless of which pharmaceuticals are used, and then weigh these costs together to see what the country pays to treat various diagnoses. The problem with this type of price comparison is difficulties in qualifying which pharmaceuticals belong to a specific therapy group, and that treatment traditions may differ between countries.

#### Pharmaceuticals with very low volumes in a country are excluded

Some countries that have a matching with a product in Sweden may exhibit sales volumes considerably lower than in Sweden. If the volume per capita is less than 0.5 per cent of the Swedish equivalent, the pharmaceutical is excluded from the bilateral index calculation. This practice is done to avoid attributing a product that has very little use in the comparison country a disproportionate weighting in the price comparison and thereby potentially overestimating the relative price level. Data on volume over a running 12-month period through March 2018 and total number of inhabitants in 2015 in the respective country are used for the calculation.

#### Sales volumes and weighting

It is common practice to weight the various product prices in a price index by volume. Price differences for products that have high sales are assigned a greater importance than products with low sales and vice versa.

A price index is a weighted average of a number of products usually calculated over time. If there are two periods (period 0 and period t) and n products, a price index is generally written as:

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

To calculate the relative importance of a product's price, it is normal to use sales volume  $q$  as a product weight. In this analysis, the index is calculated for one time period at a time, which means that period 0 and period  $t$  are the same. Time is replaced by the country: foreign U and Sweden S.

The weight can either be sales volume in a foreign country or sales volume in Sweden. The choice affects whether the price index should be interpreted from a Swedish perspective or not. The convention for price analyses is to calculate the Laspeyres price index, i.e. with the country from whose perspective the price differences should be seen as base - in this case Sweden:

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

Where  $p^U$  refers to the price in the foreign country and  $q^S$  is the quantity in Sweden. If the price is the same in Sweden and in the foreign country, the index has a value of 100. If the index is  $<100$  (or  $>100$ ), the product has a lower (or higher) price in the foreign country than in Sweden.

A price index lower (or higher) than 100 means a theoretical increase in costs (cost savings) can be achieved if the Swedish prices change in relation to the foreign prices, given that Swedish consumption is assumed to be unchanged. This is a strong and improbable assumption that requires perfectly inelastic demand. If demand is not inelastic, then the change in demand either strengthens or weakens a theoretical increase in costs or cost savings. The range of pharmaceuticals, i.e. the introduction of competing products and improvements to existing ones, is also important.

The price index gives a good overview of how the price level in comparable countries is related to the price level in Sweden during the current period. However, the absolute price index should be interpreted with caution since it is influenced by both volume and currency effects. However, this study uses a rolling exchange rate for the last three years throughout. This also applies to the index data reported for 2014, 2015, 2016 and 2017.

If another country's volume weight is used as a base instead of the home country, the absolute level of the price index is adjusted, but not necessarily the relative order between the countries. See the sensitivity analysis, which highlights the effect of using the volume weights of other countries.

#### Definition of "price basket"

To calculate a price index, whether it is bilateral or cross-sectional, the "price basket" must be defined. For a bilateral price index, the same product needs to be available in Sweden and in the comparison country to be included in the price comparison with that country.

For a cross-sectional price index, the same product needs to be available in several countries to be included in any of the countries' price indices. The threshold, referred to as degree of matching, has been set at 40 per cent in those cases where cross-sectional 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. To create the same basket for all countries, the values are filled out with Swedish prices for countries where there are no sales for a particular product.

The set limit for how many countries must have sales in order for a pharmaceutical to be included in the comparison affects both the number of values filled out and the number of pharmaceuticals that are eligible for comparison. The more stringent the matching requirement applied, the lower the amount of data that needs to be filled out, but this means that fewer pharmaceuticals are eligible for comparison. A less stringent matching requirement increases the number of pharmaceuticals in the comparison, but requires that more data be filled out with Swedish data, which tends to even out the differences between the countries. With this method, it is possible to calculate the average since the mix of pharmaceuticals is the same in all countries (the degree of filling out nevertheless varies).

Another option is to compare with the pharmaceuticals that match bilaterally in each country. This maximises the number of pharmaceuticals included in the comparison and makes it unnecessary to fill out with Swedish values when a pharmaceutical is not available in another country. The dilemma is that the mix of pharmaceuticals varies between countries. It is therefore not possible to compare price levels between countries, only the respective country's relationship to Sweden's index.

In this report, we work mainly from bilateral indices, thereby capturing all pharmaceuticals that match with each individual country. The value that these pharmaceuticals represent, compared to the total Swedish sales in the sample, varies between countries.

### Drivers

The results section analyses what drives the bilateral index change between 2014 and 2018 for each segment. Here, there is an explanation of the methodology used.

The drivers explain the bilateral index change. If a country had an index of 125 (25 percent higher prices than Sweden) in 2014, and if 2018 has an index of 150, the index change has been 20 per cent ( $150/125-1$ ).

In order to isolate the effects of currency, price and product mix, a reference value is needed, and it is set to the 2014 index for each country, excluding products for which there were no sales in 2018. The reason why products for which there were no sales in 2018 are excluded is to be able to keep the reference point constant for all effects.

*Total effect* is calculated by comparing the reference value, as explained above, from 2014 and comparing it with the 2018 index for all matching products in the bilateral index.

*Currency effect* is calculated by maintaining local prices for 2014 and Swedish volumes of pharmaceuticals from 2014, and by only allowing the exchange rate to vary from 2014 to 2018.

*Price effect* is calculated by maintaining the exchange rate for rolling three-year averages for 2014 and Swedish volumes of pharmaceuticals from 2014, and by only allowing the local price in local currency to vary from 2014 to 2018.

*Product mix effect* is calculated as a residual of the variation that remains of *total effect* that cannot be explained by *currency effect and price effect*. The variation arises from the fact that new pharmaceuticals come to the market and Sweden's volume distribution of pharmaceuticals changes over time.

For methodology on drivers of cross-sectional indices, see last year's report.

## Appendix 2: Pricing and reimbursement systems

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### Pricing models: IRP

Prices of pharmaceuticals can either be set freely by market participants or by direct or indirect regulation. A frequently used method is to consider the price level in a number of reference countries (reference pricing) or to base pricing on assessed values or profitability.

<b>1</b> Alternative method to international reference pricing	<b>a)</b> Value-based pricing	<b>b)</b> Indirect price control by assessing value and profitability	<b>c)</b> Free pricing
<b>2</b> International Reference Pricing (IRP)	<b>a)</b> Formal	<b>b)</b> Informal in combination with another method (e.g. assessment of benefit or value)	

Reference pricing, which is the most common method in Europe, can be formal or informal/supporting. This means that the average, the median or the maximum price that is calculated either directly governs the set price or constitutes a level that is considered during negotiation, during procurement or that forms part of a wider supplementary health-economic assessment.

The method for how reference countries are designated varies. In some cases, countries must be similar in terms of certain characteristics such as economy or geographic proximity. However, in most cases the reasoning behind why certain countries are defined as reference countries is not clearly justified.

The number of countries in a price basket varies greatly within Europe, from 3 to 31 countries. Consequently, this plays a major role in the extent to which an individual country's price or price range affects a price basket in another country. With average value pricing, an individual country's weighting may vary from 3 per cent up to approximately 30 per cent. The direct or indirect strength of the price impact also varies depending on whether the country applies some form of supplementary assessment in addition to international reference pricing.

Exchange rate fluctuations affect pricing in countries that use reference pricing. The rules vary whether prices can not only decrease but also increase in response to exchange rate fluctuations. Thus, these changes affect the dynamics in the prices of other countries. The Netherlands and Norway use international reference pricing and adjust a fixed price ceiling in response to factors such as exchange rate changes in the reference countries, but at a predetermined time interval. Norway adjusts price both upwards and downwards. Ireland also adjusts the set reference price in response to exchange rate changes, but only downwards (this was introduced from 2017 together with the changed composition of the country basket for price

comparisons). Other countries with reference pricing have not specifically stated whether price is adjusted for changes in exchange rates in the reference countries following the initial price decision. The following table shows how often the price is adjusted automatically in countries with reference pricing. The price is readjusted between three months to five years after a pricing decision.

Denmark, Sweden and the UK apply a different pricing method than reference pricing. Up until 2011, Germany also applied a different method, but has since transitioned to considering reference prices as part of a more extensive assessment of new pharmaceuticals.

Only a few countries in Europe apply a different form of pricing than international reference pricing. Value-based pricing is used in Sweden and the UK. Denmark uses free pricing at the AIP level, while AUP (pharmacy retail price) is regulated nationally, which means that the same prices are found in pharmacies across the country. In the UK, price is regulated through voluntary PPRS (Pharmaceutical Price Regulation Scheme) agreements with the pharmaceutical industry. There is freedom in pricing at the launch of new substances, but price is subsequently regulated by limiting the permitted profitability. The UK also assesses the pharmaceutical's value-based benefit.

Table 5: Pricing models for the 20 countries participating in the survey.

	Country	Pricing model (pharmaceuticals not exposed to competition)	# of countries	Reference countries	Method	Time for new price adjustment (Months)
1	Denmark	No IRP. Competition/price notification	-	-	-	-
	UK	No IRP. Indirect price control	-	-	-	-
	Sweden	No IRP. VBP	-	-	-	-
2a	Greece	IRP, formal	27	Other EU	Average of 3 lowest	3/6
	Ireland	IRP, formal	14	Austria, Belgium, Denmark, Spain, Finland, France, Germany, Netherlands, UK, Sweden, Portugal, Luxembourg, Greece and Italy	Average	12
	Netherlands	IRP, formal	4	Belgium, Germany, France, UK	Average	6
	Norway	IRP, formal	9	Belgium, Denmark, Finland, Ireland, Netherlands, UK, Sweden, Germany and Austria	Average of 3 lowest	12
	Portugal	IRP, formal	3	Spain, France, Italy	Average	12
	Switzerland	IRP, formal	9	Belgium, Austria, Germany, Denmark, Finland, France, the Netherlands, Sweden and UK	Average	36
	Slovakia	IRP, formal	27	Other EU	Average of 3 lowest	6
	Czech Republic	IRP, formal	*28/19	Other EU for subsidy decisions. For price decisions: Belgium, Germany, Spain, Finland, France, Netherlands, Croatia, Ireland, Italy, Lithuania, Latvia, Hungary, Poland, Portugal, Greece, Slovakia, Slovenia, Sweden, UK	Average of lowest 3	36
	Hungary	IRP, formal	31	EU and EEA	Lowest price	-
	Austria	IRP, formal	27	Other EU	Average	-
2b	Belgium	IRP, informal / supporting	27	Other EU	Average	-
	Finland	IRP, informal / supporting	29	EEA (Other EU + Norway and Iceland)	Not determined/ average	60
	France	IRP, informal / supporting	4	UK, Italy, Spain and Germany	Average/ "close" price	60
	Italy	IRP, informal / supporting	24	Other countries in the EURIPID database	Not determined / lowest price	24
	Poland	IRP, informal / supporting	31	EU and EFTA	Not determined/ average	24
	Spain	IRP, informal / supporting	*18/3	Euro countries but greater emphasis on three countries: France, Italy and Portugal	Lowest price	12
	Germany	IRP, informal / supporting	15	Austria, Belgium, Cyprus, Denmark, Greece, Spain, Finland, France, Ireland, Italy, Netherlands, Portugal, Sweden, Slovakia, UK	Weighting by market and purchasing power	-

## Pricing system in Europe

In order to set the results of the price comparison in a context, a description is given of the reimbursement and pricing systems in participating countries. This year's report includes more in-depth studies of three countries, namely Germany, the

United Kingdom and France. Then there are brief descriptions of the pricing and reimbursement systems in other countries. Germany and France have been chosen as in-depth areas because the countries are to some extent each other's opposites: While Germany is known for having high prices but also early market entry, France has lower prices but at the same time later market entry.

The German and French pricing systems have some peculiarities that are interesting from a policy point of view. In Germany, there is free pricing in the first year. In France, there is a system with varying degrees of reimbursement. The French system demonstrates relatively good price dynamics with prices falling within a few years after launch. The UK, on the other hand, is the country that is most similar to Sweden in the patterns of price dynamics and market entry. Their pricing of new pharmaceuticals is also similar to Sweden's, with ceiling prices according to value-based pricing. France and the UK both have framework agreements between authorities and manufacturers that control the development of costs by influencing price trends and volumes.

In the price comparison above, a description is given of prices over the life cycle from Sweden, Germany and France (Figure 5). The comparison shows that while pharmaceuticals are relatively expensive at launch in Germany, and where prices rise in relative terms with rising pharmaceutical age, France shows the reverse pattern. French prices are slightly lower than the average of European countries at launch, and prices fall relative to other countries with rising pharmaceutical age.

To supplement this scenario, a description follows of some studies that analyse time to market entry for the participating countries.

#### Market entry

There are several studies that show how quickly new pharmaceuticals are launched in European markets. These exhibit roughly the same pattern. For market entry, the relation is "the reverse" of the case for price dynamics. Germany is the country with the earliest market entry for new pharmaceuticals. Sweden belongs to a cluster of countries that come behind Germany (with countries like the UK, Denmark, and Finland). However, France belongs to a group of countries with relatively late market entry. Table 6 below shows the results of four studies on time-to-market in European countries.

Table 6 Time-to-market (TTM) for European countries in four different studies (months)

Vernier (2011)		EFPIA (2018)		HST (2016)		CIHI (2015)	
Country	TTM	Country	TTM	Country	TTM	Country	TTM
<b>Germany</b>	<b>0</b>	<b>Germany</b>	<b>3,5</b>	<b>Germany</b>	<b>3,5</b>	<b>Sweden</b>	<b>5</b>
Denmark	0,8	<b>UK</b>	<b>3,7</b>	Denmark	5	<b>UK</b>	<b>7</b>
<b>UK</b>	<b>0,8</b>	Switzerland	4,1	<b>UK</b>	<b>5</b>	<b>Germany</b>	<b>8</b>
Austria	1,5	Denmark	5,2	Finland	5	Switzerland	11
Switzerland	1,7	Netherlands	7,6	Austria	6	<b>France</b>	<b>13</b>
Ireland	2,6	Finland	8,3	<b>Sweden</b>	<b>6</b>	Italy	14
<b>Sweden</b>	<b>3,5</b>	<b>Sweden</b>	<b>9,4</b>	Ireland	7		
Netherlands	3,7	Norway	9,7	Netherlands	9		
Finland	4,2	Austria	11	Greece	9		
Norway	4,8	Spain	12	<b>France</b>	<b>10</b>		
Spain	6,6	Italy	13	Spain	11		
Belgium	7,2	Ireland	14	Belgium	12		
Portugal	9	Belgium	14	Italy	12		
Italy	9,6	<b>France</b>	<b>17</b>	Portugal	12		
<b>France</b>	<b>10</b>	Portugal	21				
Greece	13						

Source: Verniers et al (2011), EFPIA (2018), CIHI (2015), HST (2016). In Verniers et al. (2016) Germany is rated at 0. EFPIA (2018) indicates TTM in days, which are expressed here in months (by 30 days).

Verniers et al (2011) study time-to-market in 50 countries globally, for 58 new substances between 1994 and 2008. The study sets out TTM as a deviation from the average. Therefore, in the table above, Germany has been normalised to zero. Germany is fastest, with Sweden, the UK following and France clearly behind. In HST (2016), time-to-market is defined as the month when sales amount to 1 per cent of the maximum sales during the 24 months following market approval by EMA, for pharmaceuticals approved during 2006-2011. For Germany, the average TTM amounted to three and a half months. The UK follows Germany and is before Sweden, whose average TTM amounted to six months. However, France belongs to a group of countries with market entry clearly later. TTM was ten months in the survey. EFPIA (2018) looks at administrative times after market approval, for new substances during 2014-2016. Here too, Germany is the fastest closely followed by the UK, then Sweden and lastly France. CIHI (2015) compares time-to-market during 2009-2014 for new substances for Canada compared to seven countries, including Sweden, Germany and France. Here, however, Sweden is the fastest, followed by the UK, then Germany and lastly France.

One weakness in the studies presented above is that besides EFPIA (2018), the figures are slightly dated. Given this, the studies nevertheless show a relatively large qualitative agreement in the time ranking between the four countries, where the countries are ranked as Germany, the UK, Sweden and France according to the shortest time-to-market (but CIHI (2015) differs from this pattern).

In summary, Germany, the UK and France show differences in the relationship between price and availability. In short, the conclusion is that pharmaceuticals are expensive in Germany but quickly accessible, while in France the wait is longer but then prices are lower. The UK is in the middle. The pricing systems for the countries will be described in the following sections.

## Germany's pricing system

Germany is mainly known for its early launch of pharmaceuticals. Other characteristics of the German system include:

- A decentralised system where a large number of health insurance funds constitute the core but with centralised negotiations for patented medicines.
- A system with a guideline of twelve months. Until that time, the manufacturer's price applies. In the event of later price agreement, the later agreed price applies retroactively to the twelve-month date.
- The benefit assessment provides the basis for negotiations, rather than determining a price to be accepted.

### The German system for pricing pharmaceuticals

In Germany there is a price and reimbursement system that combines free pricing, reference pricing and value-based pricing. The reference pricing part is informal/supporting and price information is collected at “actual” ex-factory level (before transport and other distribution costs and after rebates and discounts).<sup>8 9</sup>

The German health insurance system is one of the world's oldest. In 1883, the country instituted compulsory health insurance funds, “*Krankenkassen*”. In 2018, there were 110 health insurance funds, but there have been considerably more (in 1930 there were 7,000). Traditionally, the health insurance funds have been linked to the workplace, but there are also other types of insurance funds, such as regional/local insurance funds. The health insurance funds form the basis of the German system, in the same way that county councils form the basis of Swedish health care. Most of the German population (90%)<sup>10</sup> is covered by a mandatory statutory health insurance (*GKV, Gesetzliche Krankenversicherung*). This health insurance is administered by the health insurance funds. Others are covered by private insurance. Private health insurance companies usually have the same products as GKV.

<sup>8</sup> Silke Baumann och Karam Abulzahab, Federal Ministry of Health have contributed information for the description of the German system, 9 November 2017.

<sup>9</sup> GKV-Spitzenverband has contributed information for the description of the German system, 1 June 2018.

<sup>10</sup> GKV (2018b).

Main participants:

- **G-BA** (*Gemeinsamer Bundesausschuss - Federal Joint Committee*)  
Self-governing decision-making body at national level that unites medical organisations, hospitals and health insurance funds, and which provides guidelines for the healthcare system. Formally decides on the additional herapeutic benefits of new pharmaceuticals.
- **IQWiG** (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen - Institute for Quality and Economy in Health*)  
Institute at national level evaluating the additional therapeutic benefit of new pharmaceuticals.
- **GKV-SV** (*Gesetzliche Krankenversicherung-Spitzenverband - Association of Statutory Health Insurance Funds*)  
The negotiating body at national level of the public health insurance funds. Negotiates on behalf of the public and private health insurance funds on pharmaceutical prices with the manufacturers.
- **BfArM** (*Bundesinstitut für Arzneimittel und Medizinprodukte - Federal Institute for Drugs and Medical Devices*)  
German Medicines Agency. Approves new pharmaceuticals.

All approved pharmaceuticals entering the German market are included in health insurance schemes, except those not covered by a specific law (e.g. OTC) or G-BA decisions. The patients are generally obliged to contribute to the cost of pharmaceuticals by means of a 10% contribution (at least 5 euros and a maximum of 10 euros per prescription)<sup>11</sup>.

AMNOG – Arzneimittelmarkt-Neuordnungsgesetz (*Act on the Reform of the Market for Medicinal Products*), an act that came into force on 1 January 2011 that regulates the pricing of new pharmaceuticals. According to AMNOG, the manufacturers freely set prices for pharmaceuticals at market entry.<sup>12</sup> However, they must submit documentation with necessary information for assessing the additional therapeutic benefit of the pharmaceutical. AMNOG states that a formal assessment of the "additional benefit" for new pharmaceuticals must be made by G-BA.<sup>13</sup> The price is subject to negotiation based on the assessed additional benefit within twelve months after the launch of the product on the German market. The purpose of AMNOG was to limit rising pharmaceutical costs while retaining early access to new pharmaceuticals and incentives for innovation.<sup>14</sup>

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<sup>11</sup> IGES (2018).

<sup>12</sup> VFA, How does a new drug enter the market?

<sup>13</sup> Between 2011 and 2014, 66 pharmaceuticals were evaluated, of which 27 did not show any additional benefit compared to already existing pharmaceuticals.

<sup>14</sup> German Federal Ministry of Health, Die Spreu vom Weizen trennen Das Arzneimittelmarktneuordnungsgesetz (AMNOG).

## Pricing of new pharmaceuticals I

In Germany, new pharmaceuticals are priced as follows:

	Measure	Time
1.	Market approval: After the Federal Institute for Drugs and Medical Devices (BfArM) or the European Medicines Agency (EMA) has approved a new pharmaceutical it can be launched by the manufacturer. In connection with the launch, the manufacturer presents documents to G-BA showing the therapeutic properties of the pharmaceutical. The pharmaceutical is included in the benefits scheme of the health insurance funds at a price determined by the manufacturer.	
2.	The Federal Joint Committee G-BA normally sends the documentation to the IQWiG institute, which conducts a benefit assessment of the new pharmaceutical. IQWiG responds with a statement to G-BA. Except for Orphan drugs: in this case the G-BA evaluates the new pharmaceutical.	0-3 months
3.	After consultation with the manufacturer, G-BA decides whether the new pharmaceutical provides additional benefit compared to the “state-of-the-art” therapy (corresponding products). In the event of no additional benefit, the price should not exceed the reference price for corresponding products (according to the German “healthcare standard”).	3-6 months
4.	If the pharmaceutical is considered to provide additional benefit, negotiations on the price between the manufacturer and the GKV-SV (Association of Statutory Health Insurance Funds) are initiated. There is a possible discount on the manufacturer's price. However, the manufacturer's price is valid during the first twelve months.	6-12 months
5.	If agreement is not reached, the case will be sent to an arbitration board. In arbitration, the manufacturer, GKV-SV and outside experts participate. The arbitration board decides on the price. The new price applies retrospectively to the 12-month date.	12-15 months
6.	If the arbitration board's decision is not accepted, the manufacturer may withdraw. Both sides have the possibility to go to court, which may refer the case back to the arbitration board.	Uncertain

The result of the benefit assessment – usually evaluated by IQWiG – provides no single figure for the pharmaceutical's relative cost effectiveness (similar to ICER). Instead, several parameters are presented such as: indications, therapeutic effect compared to comparators, patient groups/number of patients, the cost of comparators, the cost for the first year and reference prices.

On the basis of the IQWiG-assessment, the G-BA makes a resolution. The resolution is the basis for the GKV-SV in its negotiation with the manufacturer.

When manufacturers and GKV-SV agree on a new price, it is the new negotiated price, *Erstattungsbetrag*, a new list price (ex-factory), which forms the basis for distribution and pharmacy margins. However, the manufacturers are allowed to report the free price such as PpU, *Preis des pharmazeutische Unternehmers*, "the manufacturer's price", to price and product databases even after the first year. After year one, there will therefore be two different list prices.<sup>15</sup>

There are normally no volume restrictions during the period of free pricing, nor restrictions on certain patient groups (exceptions may apply). Older pharmaceuticals (launched before 1 January 2011) are not evaluated (exceptions may apply). It is up to the prescribing doctor if he wants to prescribe a new pharmaceutical.

If manufacturers and GKV-SV do not agree, the pharmaceutical company can withdraw the product from the German market. Under certain conditions, a health insurance fund may directly import a pharmaceutical to a patient even if it is formally discontinued on the German market. One example is Translarna.<sup>16</sup>

Evaluation and price negotiation according to AMNOG apply to all new pharmaceuticals with new active substances introduced on the German market after 1 January 2011. Exceptions exist for pharmaceuticals with annual sales within GKV of less than EUR 1 million. For orphan pharmaceuticals, additional therapeutic benefit is assumed by virtue of marketing authorisation without reference to a suitable comparator in Germany, provided that annual sales within GKV are below EUR 50 million<sup>17</sup>. When this threshold is exceeded, the orphan pharmaceutical is evaluated, and the price is negotiated the same way as all other pharmaceuticals.

#### Reference price groups and generics

Most generics and some other pharmaceuticals are included in G-BA reference price groups. These include pharmaceuticals:

- (1) with the same active substance and similar use,
- (2) with comparable therapeutic or pharmacologically active substances (usually at ATC<sub>4</sub> level) and
- (3) with comparable therapeutic effect (usually used for fixed combinations).

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<sup>15</sup> GKV (2018).

<sup>16</sup> GKV (2018).

<sup>17</sup> GKV (2018)

In 2018, the number of groups is distributed as follows:

- (1) 212 substances in 319 groups
- (2) 173 substances in 65 groups
- (3) 173 combinations in 63 groups

In 2017, the pharmaceuticals included in the reference system accounted for 81 per cent of prescriptions and 37 per cent of the turnover for pharmaceuticals within the benefits scheme.<sup>18</sup>

G-BA determines which pharmaceuticals should be included in a reference price group. GKV-SV then sets the price in the group (Festbetrag). The price is set administratively, using a statistical model. Pharmaceuticals in a reference price group are assigned a maximum price for the benefits scheme. If the price of the pharmaceutical exceeds the price, the patients pay the difference. Companies often lower their prices to match the maximum price for compensation. If they do not, patients may ask their prescriber for an alternative.

Discounts and savings

#### *Savings with AMNOG*

An important purpose of AMNOG was to save on rising pharmaceutical costs. The Association of Statutory Health Insurance Funds GKV-SV states on its website that since the introduction of AMNOG, the new system has led to the following savings:

*Table 7 Savings with AMNOG, EUR million.*

<b>Year</b>	<b>Saving</b>
2012–13	180
2014	450
2015	925
2016	1 350

Source: GKV (2018c).

In a report<sup>19</sup> published by DAK, one of the largest health insurance funds in Germany, it was stated that the average discounts for the prices negotiated, relative to the free price during the first twelve months, were 20.7 percent (102 new pharmaceuticals in the study). The pharmaceuticals were classified according to additional benefit. The following table shows the average discount per class of additional benefit.

<sup>18</sup> Bundesgesundheitsministerium, Federal Ministry of Health (2018).

<sup>19</sup> DAK (2017).

*Table 8 Discounts on new pharmaceuticals in relation to price during the first 12 months, up to 2016, average and median values for different levels of additional benefit*

<b>Additional benefit</b>	<b>Average</b>	<b>Median</b>	<b>Range</b>
Essential (1)			
Significant (28)	17.1%	18%	0.2%-45.9%
Low (30)	20.2%	18.2%	1.2%-41.3%
Not quantifiable (13)	20.4%	18.1%	9.0%-36.8%
Added benefit not proved (30)	25.1%	17.7%	3.0%-58.15

*Source: DAK (2017), p. 141. Within brackets: number of pharmaceuticals in the survey. Range indicates max-min values.*

The discounts seem to be evenly distributed regardless of the degree of therapeutic benefit that the pharmaceutical provides. Pharmaceuticals with relatively little additional benefit show a slightly higher discount. Thus, the pharmaceutical manufacturers who could not prove added benefit had to accept higher discounts after the first year.

The survey also shows average discounts for different disease groups. Among the reported diseases, the area of nervous system diseases shows the highest discounts. Lowest discounts were given in the field of infectious diseases.

*Table 9 Discounts for different disease groups, up to 2016, average values*

	<b>Average</b>
Nervous system diseases (6)	41%
Oncological diseases (37)	23%
Metabolic diseases (15)	22%
Cardiovascular diseases (5)	21%
Respiratory diseases (7)	15%
Infectious diseases (12)	12%

*Source: DAK (2017), p. 138. Within brackets: number of pharmaceuticals in the study.*

### Discounts in the German system

Within the health insurance system, discounts on the official price are common, especially for generic pharmaceuticals. Individual health insurance funds can draw up agreements on discounts on the pharmaceutical company's official price through public procurement. The prices of pharmaceuticals given 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 provide a statutory discount of 7% off the list price for patented pharmaceuticals that are not grouped in reference price groups.<sup>20</sup> Discount is also available for generic pharmaceuticals. The discount is normally 6 per cent for pharmaceuticals exposed to competition, unless the price is at least 30 per cent below the reference price.<sup>21</sup>

In addition to the statutory discounts, GKV-SV negotiates a refund rate (Erstattungsbetrag) with the manufacturers. These refund rates may replace the statutory discount in whole or in part. After seven years with AMNOG, the statutory discount is retained in fifty per cent of the cases, while the others are replaced by other (higher) discounts that are negotiated.<sup>22</sup> Refund rates and their discounts (statutory) are available in the German price database.<sup>23</sup> In addition to the refund rates negotiated by GKV-SV, local health insurance schemes can negotiate additional discounts. This is on generics and diabetes pharmaceuticals, for example, where competition is fierce. These discounts are not visible in the price database.

#### Other savings

The legislation also stipulates a price freeze on the price level that applied on 1 August 2009. It was extended to 2022. From and including 2018, prices can be adjusted according to inflation.<sup>24</sup>

Substitution at pharmacies is an important tool for holding down rising pharmaceutical costs. Pharmacists should substitute with a cheaper pharmaceutical with the same substance. If the patient's insurance scheme has an agreement for a discount on a product with the same substance as the prescribed product, the pharmacy is obliged to disclose the product for which the discount applies. However, in certain therapeutic areas, substitution is not allowed, e.g. thyroid hormones, anti-epileptic pharmaceuticals or pharmaceuticals for certain heart diseases. In all other cases, prescribers can exclude substitution for medical reasons.

At regional level, there are agreements between health insurance funds and doctor associations on additional rules for prescribing in order to hold back the cost development and stimulate more rational prescription behaviour, e.g. quotas for biosimilars. It is also possible to issue sanctions if doctors do not comply with these rules or other legislation.

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<sup>20</sup> Discounts to 2010 inclusive, ex-factory, amounted to 6 per cent on new innovative pharmaceuticals. The discount for that category increased to 16 per cent during the period 1 August 2010 – 31 December 2013. (KBV (2018) and Ruggeri, K. and Nolte, E. (2013) p. 42.)

In 2014 it was decided that the mandatory discount on subsidised pharmaceuticals would be reduced from 16 per cent to seven per cent (Tillväxtanalys (2016), p. 20.)

<sup>21</sup> KBV (2018).

<sup>22</sup> GKV (2018).

<sup>23</sup> Lauer-Fischer (2018).

<sup>24</sup> GKV (2018).

## France's pricing system

Some characteristics of the French system for pricing pharmaceuticals:

- a centralised system with volume control as an important factor.
- a three-year framework agreement between the state's negotiating body (CEPS) and the manufacturers controls the agreements between them.
- price dynamics: converts discounts to price reductions earlier in the product life cycle.
- makes a difference between price and degree of subsidy.

### The French system

In France, there is a compulsory state health insurance system. National health insurance is the main payer of healthcare, including pharmaceuticals (to about 70 per cent). 97 per cent of the French have supplementary insurance that pays the remainder<sup>25</sup>.

Important institutional elements of this process:

- **ONDAM** (*Objectif national des dépenses d'assurance maladie*) is the national budget for health expenses, which also controls the expenditure on pharmaceuticals. It is decided by the National Assembly and forms the basis for negotiations with the manufacturers on pharmaceutical prices.
- **Framework agreement** (*Accord cadre*) with the manufacturers. An important basis for negotiations between CEPS and manufacturers is the framework agreement that CEPS concludes with LEEM, the manufacturers' trade organisation. The agreement is in force for three years (the current agreement is in force from December 2015 to 2018). It applies as an addition to other provisions and forms the framework for multi-year agreements between CEPS and manufacturers, including product agreements.

The participants in the French system are as follows:

- **HAS** (*Haute Autorité de Santé*) Authority that carries out health economic evaluations. Consists of the *Transparency Commission* (*Commission de la Transparence, CT*), which evaluates therapeutic benefit, as well as **CEESP** (*Commission Évaluation Économique et de Santé Publique*), which conducts an economic assessment.
- **CEPS** (*Comité Économique des Produits de Santé*) is a state committee that negotiates with manufacturers on prices. It is separate from HAS.
- **The Ministry of Health** (*Ministère des Solidarités et de la Santé*) makes formal decisions on enrolments in the benefits scheme.
- **National health insurance**, *Assurance Maladie*, decides on the degree of subsidy.

<sup>25</sup> HST (2015), p. 70.

### Pricing of new pharmaceuticals

When a manufacturer wants to launch a pharmaceutical with subsidy, an application is sent to HAS. The Transparency Commission at HAS makes a clinical assessment of the properties of the pharmaceutical. If the pharmaceutical is claimed to be innovative and with high expected sales value, CEESP at HAS makes an economic assessment of the pharmaceutical. The manufacturer also submits a price report to CEPS, which is a price negotiation organisation independent of HAS.

The Transparency Commission makes two types of medical assessments. An evaluation of therapeutic benefit ("service") in absolute terms: Service Medical Rendu, SMR. Depending on the degree of therapeutic benefit, the pharmaceutical is given an assessment on a four-level scale (Important, Moderate, Mild, Insufficient). This rating is the basis for decisions on different degrees of subsidy.

The Transparency Commission also makes a relative assessment of the pharmaceutical's additional therapeutic benefit, ASMR (Amélioration de Service Medical Rendu), on a five-grade scale I-V (Major, Important, Moderate, Minor, No improvement). This evaluation determines the pharmaceutical's relative benefit compared to alternative pharmaceuticals and is the starting point for price negotiations.

After the evaluations, the case is sent to CEPS, which then negotiates the price with the manufacturer. For the pharmaceuticals with assessment grade I-III, the pharmaceutical is given a price guarantee: the prices will not be lower than the lowest price in France's reference countries (UK, Germany, Spain and Italy) for five years).

According to CEPS (2018b), the price is determined based on the following criteria:

1. Increased medical benefit (value ASMR)
2. Result of economic evaluation (CEESP)
3. Prices of comparable pharmaceuticals
4. Volumes, estimated or observed
5. Estimated or actual conditions for use

After the price has been agreed, the case is sent to the Ministry of Health for publication in the Journal Officiel<sup>26</sup>. The case also goes to the Social Insurance Agency, which decides on the degree of subsidy (100, 65, 30, 15, 0 percent, depending on the severity of the disease and the effect of the pharmaceutical). The case is then announced.

After five years of subsidy, HAS performs a re-evaluation of the pharmaceutical. The manufacturer must then submit new documents for the clinical use of the pharmaceutical. However, the evaluation is not as comprehensive as in the first evaluation. Determining SMR is always performed during the re-evaluation, while

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<sup>26</sup> <http://www.journal-officiel.gouv.fr/>

determining ASMR is not always performed. Decisions on subsidy apply in France until further notice. The Ministry of Health decides whether a pharmaceutical should remain in the benefits scheme after a review.<sup>27</sup>

#### Pricing of older pharmaceuticals

France has a special system for pricing older pharmaceuticals, where discounts are converted into price reductions.<sup>28</sup> Paragraph 21 of the three-year framework agreement, which governs the negotiations between CEPS and the manufacturers, 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 of three years after the pharmaceutical has obtained benefits scheme approval, CEPS will request a full or partial conversion of agreed discounts [remise conventionnelle] given according to the Social Services Act, L. 162-18.

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

- Each year, the National Assembly defines a savings target on health expenses, including on the reduction of pharmaceutical prices.
- Given pricing rules and market dynamics, CEPS sends an agreement to the manufacturer to reduce the price of a pharmaceutical.
- The manufacturer has one month to respond, but can also request consultations.
- The process continues until CEPS and the manufacturer have agreed on a new price.
- Finally, CEPS can unilaterally determine the price, in accordance with the law.

A pharmaceutical graded with a value of 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.<sup>29</sup>

In France, generic pharmaceuticals are priced at least 60 per cent lower than the original. The price of the original is reduced by 20 per cent and 18 months later the price is reduced by a further 12.5 per cent.<sup>30</sup> 18 months after the expiry of the original pharmaceutical's patent, the price of generic pharmaceuticals is reduced by a further 7 per cent.

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<sup>27</sup> CEPS (2018).

<sup>28</sup> Jonathan Rodrigues, CEPS, has contributed information for the description of the French system, 1 June 2018.

<sup>29</sup> One example is Opdivo whose list price began to fall after one year (CEPS 2018).

<sup>30</sup> Accord cadre (2015)

Biosimilars are priced 40 per cent lower than the biological original. The price of the biological original is reduced by 20 per cent. After 18-24 months, the price is further reduced, depending on the market share of the pharmaceutical. A market share of 60-100 per cent results in a price reduction of 15 per cent. A market share of 40-60 per cent results in a 10 per cent reduction in the price. A market share of 0-40 per cent means that the price is reduced by 5 per cent.

From 1 January 2015, generic prescription (INN) is mandatory. However, it is permitted to add a brand name to the prescription in addition to the generic prescription.

#### Discounts and savings in France

France distinguishes between product-based discounts and company-based discounts. Company-based discounts (Taux L) are based on the Social Security Act. The state sets a growth target for the pharmaceutical budget. Given this target, manufacturers pay rebates to the state according to a given formula, depending on the growth and market share of the companies. For 2017, the growth target for outpatient medicine was zero (0) per cent. The manufacturers then pay collective rebates on amounts in addition to the growth target, according to the following formula:

0 < Actual growth < 0.5 ; 50 per cent rebate  
 0.5 < Actual growth < 1 ; 60 per cent rebate  
 1 < Actual growth ; 70 per cent rebate

The individual contributions of the manufacturers are proportional to market shares and sales growth.<sup>31</sup>

In the case of product-based discounts, a distinction is made between "classic" discount agreements (linked to volumes, for example) and newer "performance" agreements, which are similar to risk-sharing agreements for newer products with uncertain medical effects. In 2016, the various discounts totalled just over EUR 1.2 billion.

*Table 10 Discounts for pharmaceuticals in outpatient care and company-based discounts, 2016*

	<b>MEuro</b>	
Dosage agreement	95	9%
Volume	409	41%
"First pack"	170	17%
Orphan pharmaceuticals	154	15%
"Performance" (risk sharing)	122	12%
Other	56	6%
Subtotal	1,006	100%

<sup>31</sup> URSSAF (2018).

Taux L net (statutory, company-based)	191
Total	1,235

Source: CEPS (2017), p. 30.

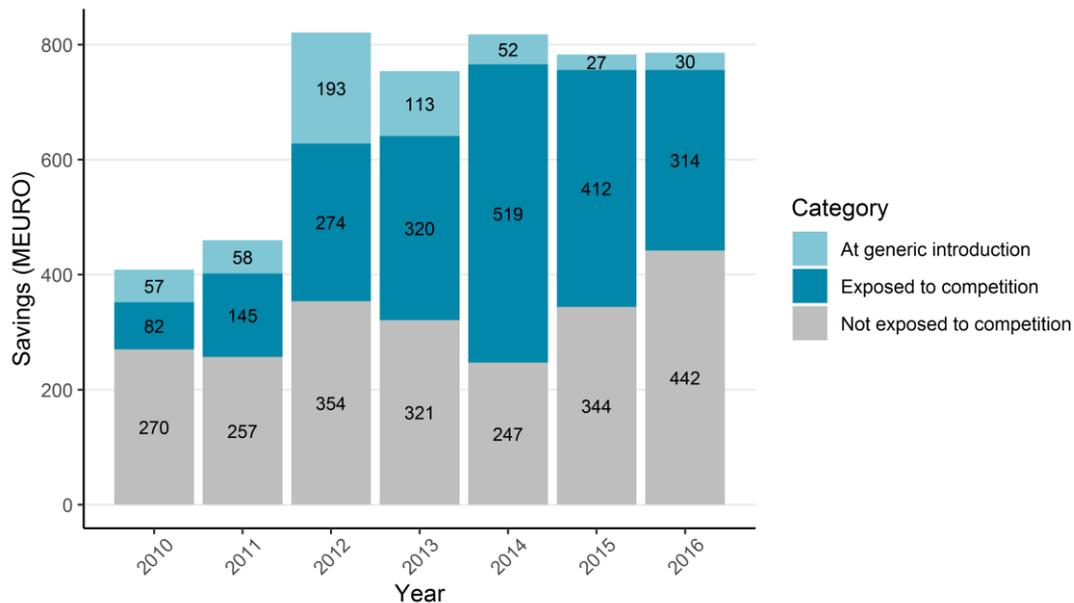
Among the product-based discounts, volume discounts accounted for 41 per cent of the total discounts.<sup>32</sup>

"First pack" is a discount that represents the difference between list price and the CEPS desired net price, where the risk of parallel export has necessitated a difference between them.<sup>33</sup>

In total, the product-based discounts amounted to around one billion euros in 2016. The state subsidy part of outpatient sales (OMNAD) amounted to about 20 billion in the same year, which is why the discounts accounted for five per cent of sales.<sup>34</sup>

CEPS also reports savings achieved through price reductions. *Figure 32* shows the savings during the years 2010-2016. In total, the savings have been around EUR 800 million per year:

Figure 32: Savings achieved through price reductions, 2010-2016 (MEuro)



Source: CEPS (2017), s. 28.

The savings resulting from price reductions on pharmaceuticals without generic competition amounted to EUR 442 million in 2016. In total, the savings through price reductions amounted to EUR 795 million. This amount is less than the savings

<sup>32</sup> A step model for discounts can be as follows (percentages for different volumes): 0-1000: 0%; 1000-5000: 30%; 5000-: 40%. A volume ceiling can be included in the agreement and if the ceiling is exceeded, CEPS may ask for a price reduction (CEPS 2018).

<sup>33</sup> CEPS (2017), p. 29.

<sup>34</sup> CEPS (2017), p. 9.

of just over EUR 1,000 million from discounts. Along with the discounts, the price reductions are about nine per cent (1.8 / 20) of the state subsidy for outpatient pharmaceuticals (OMNAD).

### Subsidies in France

In France, there are different degrees of subsidy for different types of diseases and treatments. The degree of subsidy is dependent on how the disease is classified: 100 per cent subsidy for pharmaceuticals for severe chronic diseases, 65 per cent subsidy for pharmaceuticals with high clinical effect on severe diseases, 30 per cent subsidy on pharmaceuticals with less clinical effect, and 15 per cent subsidy on pharmaceuticals with weak clinical effect.<sup>35</sup>

However, the difference in degree of subsidy is not something that affects the patient's personal finances, since 97 per cent of the population has an additional insurance that covers the cost of pharmaceuticals. Instead, the patient co-payment is a fixed fee per pack, regardless of the cost of the pharmaceutical. For those who have supplementary insurance, the patient co-payment is 0.50 euros per pack, with a high cost protection of 50 euros per year.<sup>36</sup> The patient co-payment is paid to the pharmacy; other payments become a matter between the pharmacy and the insurance company. The difference in degree of subsidy is therefore something that affects budgets within the health insurance system, rather than the economic relationship between patients and the health care system. Table 11 shows which volumes are sold within different degrees of subsidy.

*Table 11 Sales shares for pharmaceuticals of different degrees of subsidy, 2016, EUR million*

Degree of subsidy	Sales	Subsidy	Share of sales	Share of subsidies
15%	828	124	3%	1%
30%	1,996	596	7%	3%
65%	17,779	11,557	64%	59%
100%	4,350	4,350	16%	22%
Other requisition.	3,007	2,966	11%	15%
Total outpatient care	27,951	19,593	100%	100%

Source: CEPS (2017), p. 21.

Most pharmaceuticals are given a degree of subsidy of 65 per cent. These pharmaceuticals account for 64 per cent of sales. In total, the subsidy averaged 70.2 per cent of sales in 2016.

### Cost development in France

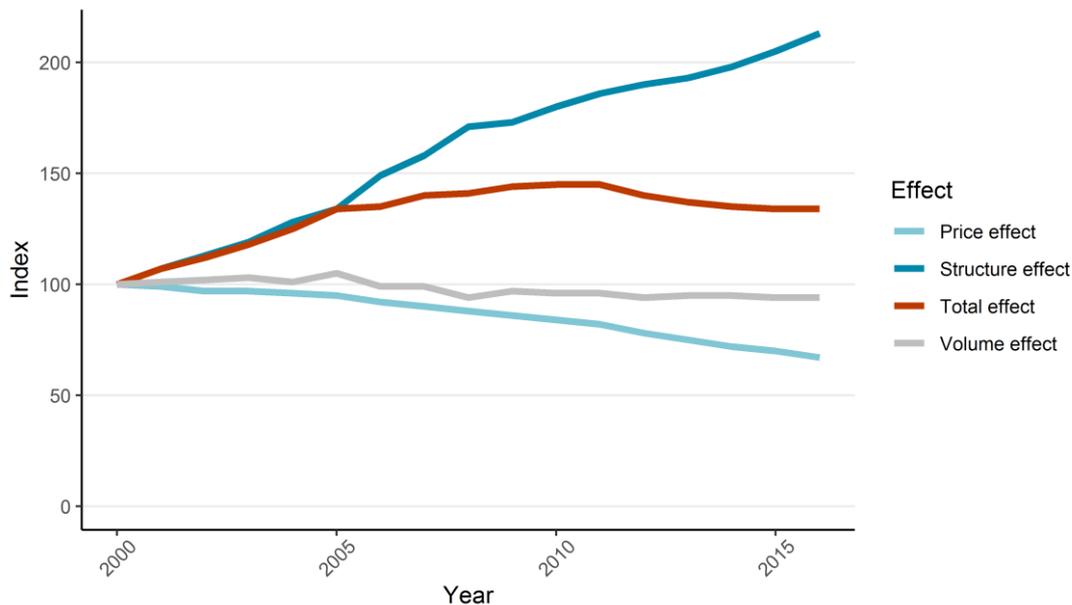
CEPS reports the development of costs for the French pharmaceutical market during the years 2000-2016.

<sup>35</sup> CEPS (2018b).

M., Falissars, B. (2013).

<sup>36</sup> HST (2015) p. 76.

Figure 33: Cost development for French outpatient pharmaceuticals, 2000-2016.



Source: CEPS (2017), p. 11.

CEPS divides the cost development into different components. A price effect that measures the change in prices. A volume effect that measures change in sold packs. And a structural effect (product mix change) that measures change in the market composition (more/fewer of relatively expensive pharmaceuticals sold).

Since 2000, French pharmaceutical costs have risen by 34 per cent. The cost increase can be attributed entirely to a structural effect, which means that relatively expensive pharmaceuticals take up a greater part. Prices have fallen during the period by 33 per cent, while volumes have remained almost still.

## The UK's pricing system

The UK system is characterised by the following:

- A system with value-based pricing similar to the Swedish system
- Manufacturers suggest a ceiling price, which is included in the benefits scheme, in the case of cost efficiency
- Relationships between manufacturers and healthcare are governed by a five-year framework agreement (PPRS)
- The framework agreement regulates the budget for older pharmaceuticals and control of profits rather than prices

### The UK system

In the UK, almost all healthcare, including pharmaceutical subsidies, takes place through the state healthcare system. Healthcare is tax-financed.

Important participants in the UK system:

- **National Health Service (NHS)** The State Healthcare System. Consists of four regional authorities (one each for England, Wales, Scotland and Northern Ireland). The system is financed through taxes. Pharmaceuticals, both in outpatient care and inpatient care, are financed through the NHS.
- **Department of Health (DoH)**. Negotiates with manufacturers and establishes rules for the NHS.
- **NICE (National Institute for Health and Care Excellence)** State Independent Authority (*Non Departmental Public Body, NDPB*, an organisation operationally independent from but responsible to the Department of Health). Carries out health economic evaluations that form the basis of subsidy decisions.
- **ABPI (The Association of the British Pharmaceutical Industry)** The original manufacturers' organisation that negotiates with the Department of Health on the forms of pharmaceutical supply to the NHS.

Important institutional elements:

***Pharmaceutical Price Regulation Scheme (PPRS)***. The relationship between the NHS and the manufacturers is regulated by a voluntary agreement: The agreement applies between the Department of Health and the manufacturers' organisation ABPI. The agreement is voluntary and lasts for five years. The current agreement (PPRS 2014) applies from 1 January 2014 to the end of 2018.

PPRS is a large document of 135 pages (by comparison, the French framework agreement between CEPS and the pharmaceutical manufacturers is 25 pages). PPRS has been in existence since 1957. The core of the agreement has been regulation of the manufacturers' profits. In recent years, the regulation of the pharmaceutical budget and value-based pricing has been added. According to the manufacturers, PPRS creates predictability.<sup>37</sup> The agreement covers about 80 per cent of the original pharmaceuticals.

***Profit regulation***. Profit regulation has been in force for over fifty years and has not changed much over the years. Manufacturers are allowed a Return on Capital (ROC) of 21 per cent. Alternatively, companies can be regulated through a target for profit margin (Return on Sales, ROS). ROS shall correspond to ROC. Most companies choose to be measured with a target for profit margin. (ABPI 2018, p. 8). There is a tolerance range for the profit level of 50 per cent.<sup>38</sup>

Within the profit ceiling, manufacturers can change their prices according to business considerations, such as prices of competitors or value-based pricing evaluation by NICE. Manufacturers can also offer or take back discounts, but this often requires dialogue with DoH. The Department of Health sets limits on what costs are allowed when assessing profits. There are percentages for what the costs

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<sup>37</sup> ABPI (2018).

<sup>38</sup> ABPI (2018).

may be for R&D, manufacturing, information, marketing and general administration.

**Statutory Scheme.** In addition to PPRS, there is also the so-called Statutory Scheme. Since PPRS is voluntary, those manufacturers that do not want to join PPRS will be regulated via the Statutory Scheme. The difference between these is primarily that PPRS aims at regulating sales and profits, while the Statutory Scheme has resulted in a more direct price control. As of 2018, this is undergoing change, see below.<sup>39</sup>

#### Pricing of new pharmaceuticals

Pricing of new pharmaceuticals takes place with value-based pricing which is reminiscent of the Swedish system. Manufacturers are free to set prices at market entry. The subsidy is governed by a negative list of pharmaceuticals that may not be prescribed with the benefits scheme. Most new pharmaceuticals are granted full subsidy in connection with market access and price being granted. However, for the pharmaceutical to be prescribed in larger quantities requires a recommendation by NICE, and then the price must be below the ceiling price that NICE determines in a health economic assessment. At launch, manufacturers can request evaluation of the new pharmaceutical by NICE. In the application, they state a requested price. NICE carries out an evaluation where value-based pricing is performed, using quality-adjusted life-years and the establishment of ceiling prices.

If NICE assesses that the pharmaceutical is cost-effective at the requested price, this is addressed in the recommendations for the NHS. The NHS must then provide the pharmaceutical at the requested price. The NHS Constitution from 2012 gives patients legal rights to pharmaceuticals recommended by NICE. NICE recommendations take precedence over local or regional recommendations. If NICE has recommended a pharmaceutical, then local or regional boards will not make any modifications or changes to this. NICE recommendations must be incorporated into local or regional regulations within 90 days.

#### Pricing of older pharmaceuticals

For original pharmaceuticals regulated under PPRS, there is no specific determination of their prices. The price of these pharmaceuticals is indirectly governed through the PPRS payment mechanism, which determines how much expenditure for older pharmaceuticals may increase (see below).

#### *Price modulation.*

PPRS also allows manufacturers to modulate the price, i.e. they can change the prices in a portfolio provided that the total effect over the portfolio will be neutral. Manufacturers can thus raise prices for any pharmaceutical and lower the price of another, provided that the price effects cancel each other out.

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<sup>39</sup> ABPI (2018).

*Statutory Scheme.*

Manufacturers that do not choose to join PPRS will instead be subject to regulation according to the Statutory Scheme. This scheme has imposed list price reductions on older pharmaceuticals. Up until 2018, the list price reduction was 15 per cent on older pharmaceuticals that were not covered by PPRS.<sup>40</sup> There is no opportunity to modulate prices and the price reduction applies to all pack sizes. However, from 2018, list price reductions are replaced by rebates on sales, see below.

*Generics*

There is free pricing for generic pharmaceuticals in the UK. This applies provided that pharmaceuticals are priced below the ceiling price that applied at the expiry of the original pharmaceutical's patent. Generic prescription (INN) is voluntary, but widely used.

Discounts and savings

Discounts and savings are mainly made according to the PPRS payment mechanism. This mechanism is new and was introduced in the 2014 agreement. The payment mechanism means that the Department of Health and ABPI agree on how much the total budget for older original pharmaceuticals may increase. If the expenditure increases to above the permitted target, a rebate is paid by the manufacturers to the NHS. In the 2014 PPRS, permitted increases, forecast increases and rebates were as follows:

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<sup>40</sup> ABPI (2018)

*Table 12 Permitted and forecast increases, as well as rebates*

	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
Permitted increase	0%	0%	1.8%	1.8%	1.9%
Estimated increase	6.3%	0.4%	2.6%	5.2%	3.4%*
Repayment	3.74%	10.36%	7.8%	4.75%	15.23%
Percentage of new pharmaceuticals	0.5%	2.7%	6.3%	9%	12.8%*

Source: Department of Health (2018). Figures with asterisk = forecast.

During the period 2014-2018, the expenditure for older original pharmaceuticals has been allowed to increase by just under two per cent per year. However, the actual increase has been greater. Therefore, repayments have been made, which varied between 4 and 10 per cent per year, depending on how much the budget has been exceeded.

New pharmaceuticals, i.e. pharmaceuticals launched after 1 January 2014, are exempt from the payment mechanism. These pharmaceuticals gradually account for an increasing proportion of the expenses for original pharmaceuticals. In 2018, they account for almost 13 per cent of the budget.

Parallel imported pharmaceuticals are also exempt from the payment mechanism since they are imported outside of the capacity of the original manufacturers.

#### *New Statutory Scheme*

In April 2018, the Government introduced changes to the Statutory Scheme. In particular, the changes meant a transition from a system with (list) price reductions to a system with rebates on sales volumes. The system of rebates for volume was considered more reliable for controlling costs. It was also thought to create a greater coherence with PPRS and its payment mechanism. The rebate for 2018 was set at 7.8 per cent, which corresponded to the percentage in the PPRS payment mechanism for 2018. For 2019, 2020 and 2021, the rebate rates are proposed to be 9.9%, 15.8% and 21.7%, which reflects the development in rebates during the voluntary agreement of 2014.<sup>41</sup> In the future, therefore, the voluntary agreement's payment mechanism will result in more direct regulation of the payment mechanism under the Statutory Scheme.

<sup>41</sup> Department of Health (2018b)

## Pricing and reimbursement systems in other countries

This section aims to improve understanding of pricing and reimbursement systems in the other countries that are analysed in TLV's annual international price comparison. The section begins with a Nordic overview, followed by information on the other countries.

### Nordic countries

#### *Sweden*

TLV determines which pharmaceuticals should be included in the pharmaceutical benefits scheme. In 2017, the cost of pharmaceuticals in the benefits scheme amounted to approximately SEK 27.3 billion, based on pharmacy sell price (AUP), including patient co-payments. The cost of prescription pharmaceuticals without benefit amounted to SEK 3.2 billion. In addition, the cost of pharmaceuticals for inpatient care amounted to SEK 8.4 billion.

For pharmaceuticals with no generic competition, value-based pricing is applied.<sup>42</sup> For generics, the product-of-the-month system is applied.

TLV's assessments are based on an ethical platform with three basic principles:

1. Human dignity principle - healthcare should respect that all people are equal in value,
2. The need and solidarity principle - those with the greatest medical need should be entitled to more of the healthcare resources,
3. Cost-effectiveness principle - the cost should be reasonable from a medical, humanitarian and socio-economic perspective.

For a pharmaceutical to be subsidised, a pharmaceutical company must first submit a reimbursement application to TLV. TLV then assesses whether the cost is reasonable for the pharmaceutical to be included in the pharmaceutical benefits scheme. The decisions are made by the Pharmaceutical Benefits Board, which is TLV's decision-making body.

### Managed entry agreements

A managed entry agreement is a contract between the county councils and a pharmaceutical company that may be considered by TLV when deciding on pricing and reimbursement status. New pharmaceuticals are becoming introduced earlier, and some pharmaceuticals are sometimes associated with uncertainties regarding use and efficacy in clinical practice. With managed entry agreements, the risk can be divided and facilitate early use, even when there is considerable uncertainty about medical effect and cost effectiveness.<sup>43</sup>

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<sup>42</sup> See for example TLV (2018e) TLV (2018f) and TLV (2018g)

<sup>43</sup> TLV (2018d).

Managed entry agreements can also be a tool for creating price competition, which lowers the costs within established pharmaceutical areas where no competition or downward pressure on prices has occurred for various reasons. One example is biological pharmaceuticals, where price competition rarely occurs despite the existence of biosimilars.

At the end of the first half of 2018, there were 40 pharmaceuticals in outpatient care that were covered by current managed entry agreements. The total cost for the pharmaceutical areas subject to managed entry agreements accounts for almost 17 per cent of the total costs for pharmaceuticals included in the benefits scheme. The total cost of medicines in the benefits scheme was approximately SEK 30 billion in 2017.<sup>44</sup>

*Table 13 Number of pharmaceuticals with managed entry agreement per area and total sales April 2017-March 2018, per area in thousands of kronor.*

<b>Area</b>	<b>Number of pharmaceuticals</b>	<b>Sales AUP running 12 months April 2018 (TSEK)</b>
Cancer	11	1,038
Factor VIII	11	558
Hepatitis C	6	1,196
TNF- inhibitors	4	2,074
Other	4	53
JAK- inhibitors	2	39
PCSK9	2	24
<b>Total</b>	<b>40</b>	<b>4,983</b>

*Source: TLV (2018), p. 33.*

Most agreements are found within the areas of hepatitis C and subcutaneous TNF inhibitors. Within these areas, sales volumes are large, treatment costs are high, and there are many competing companies. Cancer is another area with several managed entry agreements. Within this area, new pharmaceuticals are often introduced at an early stage with a high degree of uncertainty.

#### High-cost protection

The cost of pharmaceuticals within the pharmaceutical benefits scheme is included in the patient's high-cost protection. The patient pays maximum SEK 2, 250 in co-payments per 12-month period for pharmaceuticals included in the scheme. The county councils pay the rest. The national government pays annual grants to the county councils for the pharmaceutical benefits.

Since 1 January 2016, pharmaceuticals in the benefits scheme have been free of charge for children under the age of 18.

Since 1 January 2017, contraceptives in the benefits scheme have been free of charge for young adults under the age of 21.

<sup>44</sup> TLV (2018) p. 6

### Generic substitution

Generic substitution was established in Sweden in 2002 and TLV has been responsible for the so-called product-of-the-month system since 2009, where the manufacturers compete on price through a monthly auction procedure. Generic substitution leads to lower prices, and there may eventually be significant differences in price between substitutable medicines. TLV then lowers the maximum accepted sales price within the pharmaceutical benefits scheme by setting a lower ceiling price for substitutable pharmaceuticals. Each month, TLV analyses prices and sales volumes in order to find groups where the criteria for setting a ceiling price are met. TLV sets a ceiling price when the prices in a group of substitutable pharmaceuticals have dropped to at least 70 percent of their pre-competition price and when generic competition has occurred for at least six months. If the criteria are met, a ceiling price of 35 percent of the original price of the original pharmaceutical is introduced.<sup>45</sup> Setting ceiling prices in this manner reduces the price differences between substitutable pharmaceuticals within the benefits scheme. It also results in even lower costs beyond the effect of generic substitution itself.

The purpose of the pharmaceutical substitution system at pharmacies is to keep down the costs of pharmaceuticals for society. Products-of-the-month are the substitutable pharmaceuticals that have the lowest price and that the pharmacies offer their customers when they replace pharmaceuticals. Each month, the product in each package size group that has the lowest unit sales price and that the pharmaceutical company has confirmed can be provided to the entire market for the entire pricing period is designated as the product-of-the-month by TLV. Which substitutable pharmaceutical has the lowest price may vary, which means the pharmacies may offer different pharmaceuticals at different times. TLV also designates two back-up products that pharmacies can switch to if they cannot obtain the cheapest product.

Some older pharmaceuticals have no or only weak generic competition. This could be because, for example, it is not possible to substitute an original pharmaceutical with a generic one or the pharmaceutical is a biopharmaceutical. In January 2014, a price reduction was introduced for pharmaceuticals that are more than 15 years old, are included in the pharmaceutical benefits scheme, and have no or only weak generic competition. The price reduction equals 7.5 percent of the price that applied in October 2012.<sup>46</sup>

For prescription pharmaceuticals that are not included in the benefits scheme, free pricing applies. Patients either pay the entire cost themselves or, in some cases

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<sup>45</sup> TLV (2018h).

<sup>46</sup> TLV (2018i).

including pharmaceuticals for infectious diseases, the county council covers the entire cost.

## Finland

Finland applies informal reference pricing. Since 2014, the reference countries are EU 27 and Norway and Iceland. In addition to reference prices, factors such as therapeutic value, benefit and price of similar products are taken into consideration.<sup>47</sup>

### *Original pharmaceuticals: time-limited benefits*

When pricing new pharmaceuticals, the following factors are considered:

- 1) the prices in Finland of the corresponding pharmaceutical preparations used for the treatment of the same disease,
- 2) the prices of the pharmaceutical preparation in other countries of the European Economic Area,
- 3) the healthcare costs that the use of the pharmaceutical preparation entails and the benefit that can be achieved for the patient and the total costs in the health and social care,
- 4) the benefits and costs of other available alternative treatment methods,
- 5) the funds available for remuneration.

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

For pharmaceuticals with new substances, price and reimbursement status are decided for a period of maximum three years. After this period, the company needs to reapply for the pharmaceutical to be included in the benefits scheme. For other products, the decision applies for a period of a maximum of five years.<sup>48</sup>

### *Reference price groups with "price-of-the-period"*

In Finland there is a system of price bidding in reference price groups that has some similarities with the systems for the product-of-the-period in the Netherlands, Sweden and Denmark. However, in Finland, the supply period is three months instead of one month as in Sweden. The price of other substitutable pharmaceuticals in the substitute group may change during the three-month period.<sup>49</sup>

The system means that pharmaceuticals at the ATC-5 level (pharmaceuticals with the same substance) are divided into reference groups. A reference price group assumes that there is at least one generic, parallel imported or parallel distributed

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<sup>47</sup> HILA (2018)

<sup>48</sup> Kela (2017)

<sup>49</sup> COWI (2014), p.9.

pharmaceutical. The bidding process is thus applied not only to generics but also to pharmaceuticals traded in parallel.

For generic pharmaceuticals in Finland, the first subsequent product for an original pharmaceutical is priced at least 50 per cent lower than the original. The price of any subsequent generic pharmaceutical may not exceed the set price. For certain products, the level is 40 per cent. One change introduced for original pharmaceuticals from 2016 is that the original price shall be reduced by 40 per cent nine months after it is first exposed to generic competition in order to retain reimbursement status.

Since 2016, pharmacies are required to inform customers about which pharmaceuticals have the lowest price in the substitution group when dispensing products.

21 days before a new substitution period begins, Kela submits information to the pharmaceutical companies about which price applies at the start of the three-month period. The reference price is calculated based on the pharmaceutical companies' price notifications by adding 0.50 euro to the price of the product with the lowest price in each substitution group (substance and biological equivalent). The calculated reference price is a maximum price used to calculate degree of subsidy. If the price of the pharmaceutical is less than the calculated price, the subsidy calculation is deducted from the pharmaceutical price.<sup>50</sup>

For the first two weeks of the three-month period, the price set by Kela applies. However, a pharmaceutical company may adjust the price of the pharmaceutical when the database is updated with a new publication of the price list. If the pharmaceutical is not part of the benefits scheme, the pharmaceutical company can set the price freely. The price of any pharmaceutical in the benefits scheme may not exceed the price set by the Pharmaceuticals Pricing Board.

Due to price competition, prices of many pharmaceuticals change two weeks after the reference prices come into force (the 15th of January, April, July and October). What usually happens is that products with prices exceeding the reference price are lowered to the reference price level and the products with prices below the reference price are raised to the reference price level. In practice, this means a system of several "*products-of-the-period*".<sup>51</sup>

### High-cost protection

In Finland, the general rule is that all patients receive financial compensation for pharmaceuticals where the Pharmaceuticals Pricing Board has decided that reimbursement applies. The ceiling for co-payments amounts to EUR 605 per year.

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<sup>50</sup> Kela (2017)

<sup>51</sup> Kela (2018a).

From 2016, a stepped system for co-payments was introduced. This means that all patients over the age of 18 pay €50 euros before any subsidy is applied.<sup>52</sup>

There are three categories of pharmaceutical subsidies;

*Table 14 Subsidy levels in Finland and share of benefits, 2017.*

	<b>Subsidy level</b>	<b>Share of benefit</b>	<b>Diseases</b>
Basic compensation	40%	22.4%	
Lower special comp.	65%	17.4%	11 chronic diseases
Higher special comp.	100%	49.3%	34 chronic diseases
(Other subsidies)	-	10.9%	

*Source: Kela (2017).*

Basic compensation covers 40 per cent of the pharmaceutical's price or calculated reference price (22.4% of the benefits scheme cost). Lower special compensation covers 65 per cent of the pharmaceutical's price or calculated reference price (11 chronic diseases) (17.4%). Higher special compensation covers 100 per cent (34 serious chronic diseases) (49.3%) but the patient then pays 4.50 euros each time the prescription is filled.<sup>53</sup> The remaining 10.9% of the benefits scheme cost is attributable to payment of other subsidies.<sup>54</sup>

The dispensing fee is 2.50 euros per prescription during the year that a patient has exceeded the co-payment ceiling.

#### *Managed entry agreements*

During 2017, risk sharing/managed entry agreements have been introduced in outpatient care. A total of 7 agreements were concluded during the year. Since 2017, prescribers have also been required to prescribe the option with the lowest cost when biosimilar products are available, or to explain the choice of a more expensive pharmaceutical in the medical record. The changes are expected to result in savings of EUR 134 million for outpatient pharmaceuticals.<sup>55</sup>

#### **Norway**

In Norway, the price of outpatient pharmaceuticals is set in relation to the price level in other countries through formal reference pricing, and the ceiling price for prescription pharmaceuticals is regulated by the Norwegian Medicines Agency (Statens Legemiddelverk).<sup>56</sup> Norway's reference countries are: Belgium, Denmark,

<sup>52</sup> Kela (2018b).

<sup>53</sup> Kela (2016b).

<sup>54</sup> Kela (2017) p. 80

<sup>55</sup> Kela/Fpa (2018)

<sup>56</sup> Norwegian Medicines Agency (2018a).

Finland, Sweden, Ireland, United Kingdom (NHS), Germany, Netherlands and Austria. The system was implemented in 2002. The calculation is made at the AIP level. The ceiling price is set by taking the average market price for the product in the three countries with the lowest price and then adding a fixed trade margin. The focus of comparison is the price for the same product, and the comparison is made regardless of whether the product is marketed under different names in the reference countries. The calculation uses the exchange rate for at least the average of the last six months according to the compilation by central bank of Norway (Norges Bank).

The timing of price reviews is predetermined and takes place on a regular basis, which means that price adjustments for specific ATC groups are implemented every month. It is also possible for companies to apply for price review. The prices of the 250 substances with the highest turnover are adjusted according to price changes in the comparison countries or to address major changes in exchange rates, however this is done no more than once per 12-month period. The pharmaceuticals included in this annual price review represent about 70-80 per cent of the market.

*Generics: Stepped pricing model with volume component*

Generic pharmaceuticals are subject to the *trinnprismodellen* (the Norwegian stepped pricing model), which was introduced in 2005 and regulates the maximum sales price at the pharmacies.

The price is decreased in steps depending on sales volume.<sup>57</sup> When generic competition arises, the price of the original pharmaceutical is reduced by 35 per cent when the patent expires. The second step in the model occurs six months after this. The maximum price is then 59 to 81 per cent lower than the price of the original pharmaceutical at the time of patent expiry. The third step occurs 18 months after generic competition has arisen. The maximum price is then 69 to 90 per cent lower than the price of the original pharmaceutical at the time of patent expiry. A larger price reduction is applied to substances with high turnover.<sup>58</sup>

*Table 15. Trinnprismodellen/Norwegian stepped pricing model*

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

Source: Norwegian Medicines Agency (2018b).

The system for setting the ceiling price and the stepped pricing model apply to both parallel imported and directly imported pharmaceuticals.

<sup>57</sup> Norwegian Medicines Agency (2018b).

<sup>58</sup> Norwegian Medicines Agency (2015).

Pharmacies can negotiate purchase prices with the manufacturers. In practice, there is only negotiation in relation to generic pharmaceuticals. Negotiation of purchase prices for original pharmaceuticals is more limited.

Pharmacies are expected to switch to the cheapest pharmaceutical when there are several options on the *Byttelistan* (substitution list).<sup>59</sup> If a patient does not accept generic substitution, they must pay the additional cost.<sup>60</sup>

Since April 2017, there have been managed entry agreements within the framework of outpatient care. Separate agreements have been entered for two products: Repatha and Praluent.<sup>61</sup>

### *H- prescriptions*

In addition to the prescribing of common outpatient prescriptions, Norway also has what is known as H-prescriptions, which make it possible for some inpatient pharmaceutical to be collected at regular pharmacies. The H-prescription system has existed since 2006 and has been extended several times. There is joint procurement organisation for inpatient care products, Hospital Purchases, whose function is similar to that of Amgros in Denmark with the aim of obtaining discounts on inpatient medicines.

The objective of reducing costs has also led to the gradual transfer of purchases and management of certain pharmaceutical groups in Norway from outpatient care to inpatient care. TNF-alpha inhibitors have been managed within inpatient care since 2006. MS medicines were transferred to inpatient care in 2008. Some oncology medicines were transferred to inpatient care in 2014. Financial responsibility for pharmaceuticals to treat hepatitis C, blood coagulation and clotting factors, and growth hormones was transferred to inpatient care in 2016.<sup>62, 63</sup> Additional pharmaceutical groups have been subsequently transferred to management via H-prescription, including medicines for the treatment of pulmonary arterial hypertension (PAH) from January 2017 and many oncology medicines from May 2017.<sup>64</sup>

### High-cost protection

The degree of subsidy is generally 62 per cent of the cost of the pharmaceutical, but different conditions apply. The degree of subsidy is 100 per cent for children under

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<sup>59</sup> Norwegian Medicines Agency (2018d).

<sup>60</sup> Norwegian Medicines Agency (2018c).

<sup>61</sup> Norwegian Medicines Agency (2018e)

<sup>62</sup> Norwegian Society for Medical Informatics. (2016).

<sup>63</sup> Norwegian Medicines Agency (2016a).

<sup>64</sup> Norwegian Directorate of Health (2018).

the age of 16 and pensioners with low incomes, as well as for pharmaceuticals for treating infectious diseases such as tuberculosis, hepatitis C and HIV. However, a limit has been set so patient co-payments are maximum NOK 520 per prescription. A ceiling for co-payments is set each year. The 2017 ceiling is NOK 2,205.

#### Denmark

Denmark applies free pricing for list prices at the pharmacy purchase price (AIP) level. This applies to both original pharmaceuticals and pharmaceuticals exposed to competition. Prices of pharmaceuticals are reported to the Danish Medicines Agency, which in turn publishes the sales price and the subsidised price. The pharmacy retail price (AUP) is regulated through fixed dispensing fees and a percentage margin on the AIP. In Denmark, however, it has become more common for pharmaceuticals to be bought up through Amgros, the hospital system's acquisition organisation, and to be handled within the framework of inpatient care. The role of free pricing for the price of pharmaceuticals has therefore decreased.

#### *Prices are set every other week*

Denmark has a substitution system similar to the Swedish product-of-the-month system. Pharmaceutical producers can announce price and product range changes as often as every fourteen days. The product with the lowest price in the respective group automatically becomes the highest compensation that is subsidised.<sup>65</sup>

Products-of-the-period in Denmark become class A products during the period in question. Pharmaceuticals are categorised as class B if they are within a so-called bagatelle limit. If a doctor has prescribed a class B product, the pharmacy is not required to replace it with an A class product. However, the subsidy is limited to the subsidy of the relevant class A product. The bagatelle limit is between DKK 5 and 20 depending on the pharmaceutical's price.<sup>66</sup> Class C products that exceed the bagatelle limit must be substituted unless otherwise specified to the pharmacist by the doctor or patient.

The Danish Association of the Pharmaceutical Industry, the government and the regions in Denmark have entered into price-capping agreements for pharmaceuticals for a number of years. The current agreement runs from 1 April 2016 - 31 March 2019. This means that the reference price model for list prices within inpatient care must undergo a conversion, resulting in a price reduction of 10 per cent over a three-year period.<sup>67</sup> The agreement also ensures that the price of new inpatient pharmaceuticals does not exceed the average price in Sweden, Norway, Finland, the UK, the Netherlands, Belgium, Germany, Ireland and Austria.

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<sup>65</sup> Danish Medicines Agency (2018a).

<sup>66</sup> COWI (2014), p.32.

<sup>67</sup> Ministry of Health and the Aged (2016).

### High-cost protection

Pharmaceutical companies apply for benefits scheme status with the Danish Medicines Agency.<sup>68</sup> The reimbursement can be general or individual. Individual reimbursement can be granted for pharmaceuticals without general reimbursement. In such cases, the doctor applies for reimbursement on behalf of the patient. The compensation is 80 per cent of the price. The general reimbursement is a positive list and can be limited to an indication group or a patient group.<sup>69</sup>

The general reimbursement and co-payment thresholds are as follows 2018: 0 per cent of the cost up to DKK 965, 50 per cent of costs between DKK 965 and 1,595, 75 per cent of costs between DKK 1,595 and 3,455, and 85 per cent of costs over DKK 3,455. Co-payment is capped at DKK 4,030 per year. Children under the age of 18 are subject to different reimbursement thresholds than adults.<sup>70</sup>

Since 2015, pharmacists have been allowed to open up to seven pharmacies within a 75-kilometre radius. The increase in the number of pharmacies is intended to give patients greater access to pharmacies.

### Rest of Europe

#### *The Netherlands*

It is mandatory for people living and working in the Netherlands to have a basic health insurance. The content of this insurance is determined by the state and is equal for everybody. Most of the healthcare costs are covered by the basic health insurance and it is financed through fixed insurance premiums paid by everybody over the age of eighteen. There are essentially two financial schemes for health insurance; either the insurance company covers all costs for the collection of prescriptions, or the policy holder pays the outlay and submits a claim for reimbursement at the end of the insurance period. The state decides which pharmaceuticals will be included in the benefits scheme (Geneesmiddelenvergoedingssysteem (GVS)). The Dutch Ministry of Health, Welfare and Sport sets ceiling prices twice a year according to the Medical Products Award Act (Wet Geneesmiddelen prijs (WGP)).<sup>71</sup>

Reference pricing to set the ceiling price is applied to all pharmaceuticals in both outpatient and inpatient care. The Netherlands includes Belgium, France, Germany and the UK in its reference price basket. A price review takes place every six

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<sup>68</sup> Danish Medicines Agency (2018c).

<sup>69</sup> Danish Medicines Agency (2018d).

<sup>70</sup> Danish Medicines Agency (2018e). The highest annual cost for children under the age of 18 is DKK 4,030. 60% subsidy for costs between DKK 0-965, 60% for costs between DKK 965-1,595, 75% for costs between DKK 1,595-3,455.

<sup>71</sup> SFK (2017)

months, taking into account price changes in the reference countries as well as exchange rate changes.<sup>72</sup> Internal reference pricing is carried out each month.

The Dutch Ministry of Health, Welfare and Sport can continue to set ceiling prices for pharmaceuticals after 2012 but is not obliged to do so.<sup>73</sup> Since 2005, there is greater emphasis on health economic assessments for certain types of pharmaceuticals. The pharmaceuticals must undergo a cost-effectiveness evaluation before a decision about reimbursement is made. Pharmaceuticals that are managed within outpatient care and have an expected budget impact of over EUR 2.5 million must undergo a health economic evaluation.

#### *Managed entry agreements*

Risk sharing agreements have become more common in the Netherlands in recent years. Such pharmaceuticals are usually managed within inpatient care, although risk sharing agreements exist within outpatient care, such as Hepatitis C medicines. Since 2012, TNF-alpha inhibitors are only managed within inpatient care to more effectively reduce pharmaceutical costs.<sup>74</sup> The purpose of the change was that inpatient care, together with insurance companies, could act with more bargaining power as a procurer and thereby reduce the price. Hospitals also partner with each other to get discounts from manufacturers.

#### *Generics*

The insurance companies negotiate “*products of the month*” in different pharmaceutical groups through different approaches:

- Disclosed preference policy* (lowest published price of the manufacturer)
- Non-disclosed preference policy* (lowest confidential price of the manufacturer)

Insurance companies can choose to only subsidise the “*product-of-the-month*” at the pharmacies. A pharmaceutical that has the lowest price within the pharmaceutical group becomes “*preferred product*”. This applies for a fixed period of time, which varies between 1 and 24 months. However, there are insurance companies that apply even longer periods. The insurance companies apply different variants of the preference policy for preferred products, “*product(s)-of-the-month*”. The only rule is that there must be at least two pharmaceuticals within the same grouping according to substance, form and strength.

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<sup>72</sup> Medical expenses (2018).

<sup>73</sup> There are several regulations in the Netherlands that aim to limit and control state spending on prescription drugs. Medicine Price Act (Wet Geneesmiddelenprijzen (WGP)) and subsidy system (Drug Reimbursement System (GVS)).

<sup>74</sup> In 2014, an insurance company together with 12 hospitals purchased TNF-alpha drugs together to keep costs down.

See more in the Government of the Netherlands document Medicines Policy Plan: New drugs available to patients at an acceptable cost, 29 January 2016.

<https://www.government.nl/topics/medicines/documents/letters/2016/03/07/medicines-policy-plan-new-drugs-available-to-patients-fast-at-an-acceptable-cost>

Pharmaceuticals are prescribed generically. The pharmacist at the pharmacy where the medicine is dispensed decides which package is dispensed. Prescribers can cite medical need and indicate that they object to substitution. If a patient does not want the preferred product, they must pay the entire cost, except in cases of special medical need.

The price of pharmaceuticals dispensed at pharmacies can vary depending on which insurance company the patient is insured with. Either the lowest price is applied according to the G standard, or the list price is used and the pharmacy receives a rebate/discount according to a special agreement with the insurance company from the manufacturer.<sup>75</sup>

In 2008, several insurance companies (Menzis, VGZ, CZ and Agis) announced their intention to expand application of *preference policies*. The first national tender process by the insurance companies was carried out in June 2008 and led to a price war between generic pharmaceutical suppliers. In connection with this process, the price of generic pharmaceuticals with high sales fell by about 90 per cent.<sup>76</sup>

The price pressure of the tender process generated extra earnings for the insurance companies, which led to the Dutch Ministry of Health, Welfare and Sport reducing the financial grant the state gave to the insurance companies in 2009. Also in 2009, the insurance company VGZ developed a hidden pricing model in which the pharmaceutical manufacturer was able to maintain a high list price while offering VGZ a negotiated discount. This procedure was met with criticism because the benefit that the insurance company received as a buyer was not transparent to outsiders, while pharmacies dispensed certain pharmaceuticals that were more expensive than the lower-cost generic pharmaceuticals available.

## Belgium

### *Original pharmaceuticals*

Belgium has been using informal/supporting reference pricing since 2001. The reference countries consist of the EU27. The manufacturer is required to disclose the sales price (ex-factory) in other European countries where available. A national price comparison is carried out as a complement. The total economic impact of the pharmaceutical and the price level of similar pharmaceuticals in Belgium are also examined. The set price is a ceiling price for the manufacturer. The maximum mark-ups and margins are then set for distributors and pharmacies based on national regulation of both the margin (in per cent) and the total maximum mark-up on distributor (wholesalers) purchase prices and within the pharmacy chain.

### *Generics*

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<sup>75</sup> Ruggeri, K. and Nolte, E. (2013) and Zuidberg, C. (2010).

<sup>76</sup> SFK (2015) p. 19-20.

Generic pharmaceuticals are also subject to price regulation in Belgium. The price is reduced immediately when generics enter the market (in a reference cluster). The highest price for a generic product cannot exceed the price of the most expensive product in the same reference cluster. The price of the first generic product is set 43.64 per cent lower (without reference cluster) or 51.52 per cent lower (ex-factory) depending on the reimbursement category.

With generic prescribing, pharmacies substitute the cheapest alternative for pharmaceuticals included in the reference price system.

The pricing of combination pharmaceuticals (pharmaceuticals with more than one active substance) was adapted in March 2017. Combination pharmaceuticals whose patents expired, but are not included in the benefits scheme, are reviewed when one of the active substances in the combination pharmaceutical is included in the benefits scheme. The price and degree of subsidy for the combination pharmaceutical can never exceed the sum of the corresponding mono substances.

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

#### *Austria*

Austria applies formal reference pricing. Price information is collected at the ex-factory level. The price of outpatient pharmaceuticals in the benefits scheme is regulated nationally at the DIP level (distributor purchase price). Price review is carried out after 6, 24 and 48 months from the pharmaceutical's entry into the market.

Price is determined after price negotiations between the manufacturer and the Ministry of Health (BMG) in consultation with the national pricing committee. In these negotiations, the average price in the EU constitutes a ceiling price. In order to calculate the average price, the manufacturer needs to provide information about the pharmaceutical's availability in other EU markets and state the prices in these countries.

Pharmaceuticals are categorised in different colour schemes for benefits: green, orange, yellow and red. For pharmaceuticals in the green category, the price must be below the average price in the 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 deemed to be of additional benefit, as well as essential pharmaceuticals, are categorised in the orange category. In order for a reference price to be calculated, there must be price information from at least two other countries. Statutory discounts, for example in Germany, Ireland and Greece, are taken into account. Exchange rates are calculated as the average for the last month.

#### *Generics*

Since April 2017, Austria distinguishes 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.

To retain benefits scheme status, the price of the original product must be reduced by 30 per cent within three months from the date a first generic enters the market. The first subsequent product is priced at least 28.6 per cent lower than the original's reduced price. The second subsequent product is priced 18 per cent lower than the first subsequent one. If there is a third subsequent product, it is priced 15 per cent lower than the second subsequent product. Thereafter, all comparable products must have the same price level as the third subsequent product within three months.<sup>77</sup>

For biosimilars, the price of the original product must be reduced by 30 per cent after the first biosimilar enters the market in order to retain its benefits scheme status. The first biosimilar is priced at least 11.4 per cent lower than the reduced price of the biological original. The second subsequent biosimilar is priced 15 per cent lower than the first subsequent one. If there is a third subsequent biosimilar, it is priced 10 per cent lower than the second subsequent biosimilar.<sup>78</sup>

In order for products to retain their benefits scheme status, both the original and the subsequent products must apply the price of the third generic product or biosimilar.

Patients pay a fee per prescription at the time of dispensing. The fee is adjusted annually. The fee for 2017 is 5.85 euros. Co-payment is capped at 2 per cent of a patient's annual income.

## Ireland

Ireland applies reference pricing.<sup>79</sup> Manufacturer prices are set based on the average price in the reference countries (ex-factory) adjusted for exchange rate differences.

### *Framework agreement*

On 20 July 2016, the Irish Government and the Irish Pharmaceutical Healthcare Association (IPHA) entered into a new framework agreement on pharmaceutical supply effective from 1 August 2016 through 31 July 2020.<sup>80</sup> 38 pharmaceutical companies are part of the IPHA.<sup>81</sup> Appended to the industry agreement are

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<sup>77</sup> PPRI (2015a).

<sup>78</sup> Herzig (2017).

<sup>79</sup> Health Service Executive (2018).

<sup>80</sup> Department of Health; Ireland (2016b).

<sup>81</sup> Department of Health; Ireland (2016b), Schedule 2.

principles documents describing assessment of new pharmaceuticals. The agreement is expected to generate EUR 600 million in savings during the period.<sup>82</sup>

According to the agreement, the price of pharmaceuticals must be set annually based on the average price in 14 reference countries (Belgium, Denmark, Finland, France, Greece, Italy, Luxembourg, Netherlands, Portugal, Spain, UK, Sweden, Germany, and Austria).<sup>83</sup>

Price review takes place every year, with reference pricing serving as the main criterion. The first time under the new agreement was 1 August 2016.<sup>84</sup> Thereafter it is set for 1 July 2017<sup>85</sup>, 2018<sup>86</sup> and 2019. Exchange rate fluctuations are also given consideration in the price review. Prices are only adjusted downwards.

The agreement also specifies that the discount (*PCRS (Community Schemes) Rebate*) on pharmaceuticals currently amounts to 5.25 per cent in sales value, an increase from 4 per cent compared to 2016. The discount increases by 0.25 percentage points to 5.5 per cent from 1 August 2018.

The agreement also specifies a new discount for inpatient pharmaceuticals. It amounts to 5.25 per cent of the sale value from 1 June 2016 and increases to 5.5 per cent from 1 August 2018.

### Generics

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

In Ireland, generic pharmaceuticals are priced 50 per cent below the price of original pharmaceuticals. When a generic pharmaceutical enters the market, the price of the original pharmaceutical is reduced by 30 per cent within 60 days and by a further 20 per cent the following year.<sup>87</sup>

Biopharmaceuticals (*Patent-Expired Non-Exclusive Biologic Medicine*) are priced 20 per cent below the previous price of the biological original. When a biosimilar enters the market, a discount must of 12.5 per cent be given on the reduced price.<sup>88</sup>

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<sup>82</sup> Department of Health; Ireland (2016).

<sup>83</sup> Department of Health; Ireland (2016).

<sup>84</sup> HSE (2016)

<sup>85</sup> HSE (2017)

<sup>86</sup> HSE (2018)

<sup>87</sup> COWI (2014), s. 110

<sup>88</sup> Paragraph 8.1.3 in Framework Agreement (IPHA (2017)).

There are essentially four systems for the benefits scheme.<sup>89</sup>

- General Medical Services (GMS) - 2.50 euros co-payment per product and 25 euros per family and month.
- Drugs Payment Scheme (DPS) - ceiling for co-payment amounting to 134 euros per month.<sup>90</sup>
- Long-term Illness Scheme (LTI) - 16 medical conditions have special coverage. The degree of subsidy amounts to 100 per cent for individuals.<sup>91</sup>
- High Tech Scheme (HT) - pharmaceuticals prescribed in hospitals but dispensed at pharmacies.<sup>92</sup> Examples are rejection inhibitors and pharmaceuticals used in conjunction with chemotherapy or growth hormones. Patient co-payment amounts to 62.03 euros when pharmaceuticals are collected at a pharmacy when dispensed and 30.26 euros during months when no pharmaceuticals are collected. Patients who collect pharmaceuticals for medical conditions under LTI are exempt from co-payment, including for pharmaceuticals within High Tech. For others, there is a co-payment ceiling of 134 euros per month under the DPS.

100 per cent subsidy applies after a special direct payment has been made.

#### Italy

Italy adopted informal reference pricing in 2001. Reference pricing is not the main criterion, but it does support the decision-making process and is used in negotiations with the price committee. In negotiations with the price committee, issues taken into consideration include the following:<sup>93</sup>

Cost-effectiveness of the pharmaceutical in the absence of other effective therapies,  
Risk/benefit compared with alternative pharmaceuticals for the same indication,  
Therapeutic cost per day compared to products with the same efficacy,  
Assessment of the economic impact on the national healthcare system,  
Data on price and use in other European countries. Reference price information is collected at the ex-factory level. Reference price reviews take place every 24 months.

It is possible for pharmaceutical companies to apply for a premium price for innovative products.<sup>94</sup>

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<sup>89</sup> HSE (2018b)

<sup>90</sup> HSE (2018c).

<sup>91</sup> HSE (2018d).

<sup>92</sup> High tech list February 2017.  
<http://www.hse.ie/eng/staff/PCRS/items/Feb%202017%20High%20Tech%20Listing.pdf>

<sup>93</sup> ISPOR Italy Pharmaceuticals.

<sup>94</sup> ISPOR Italy Pharmaceuticals.

Italy has implemented far-reaching decentralisation of responsibility within healthcare, and it began regionalisation in 2001. The different regions in Italy have the freedom to determine the levels of patient co-payments and can thereby control their costs and budget outcomes.

Co-payments vary between regions (varies from 1 to 8 euros). There is no percentage degree of subsidy.

In Italy, generic pharmaceuticals are priced at least 20 per cent lower than the reference price of the original pharmaceutical.

Generic prescribing (INN) is mandatory in Italy. Pharmaceutical names may only be stated if specific medical reasons exist.

### Portugal

Portugal adopted formal reference pricing in 2003. The reference countries are Spain, France and Italy. Price information is collected at the ex-factory level. Reference price reviews take place every 12 months.

During the period from the second half of 2010 to March 2013, a 6 per cent reduction of the maximum price for pharmaceuticals accepted in the benefits scheme was implemented. A price reduction of 7.5 per cent was implemented in 2011, but only for specific biopharmaceuticals. Official list prices at that time should not have taken this discount into account, according to Vogler et al (2011).

### *Degrees of subsidy*

The degree of subsidy is 100 per cent for pharmaceuticals for specific defined diseases such as HIV and Alzheimer's disease. For other prescription medicines, the level is 90 per cent for critical pharmaceuticals for chronic diseases, 69 per cent for critical pharmaceuticals for serious diseases, 37 per cent for non-priority pharmaceuticals with therapeutic benefit, and 15 per cent for new pharmaceuticals whose therapeutic benefit has not been established.

### *Generics*

In Portugal, generic pharmaceuticals are priced up to 50 per cent lower than the original. If the price of the reference product is below 10 euros, the generic pharmaceutical is priced 25 per cent lower than the original.

A new law on generic prescribing (INN) entered into force in 2015.

### Switzerland

Switzerland applies formal reference pricing, in combination with value-based pricing ("national therapeutic comparison"). The average price of pharmaceuticals in nine countries is used as reference. Price information is collected at the ex-factory

level.<sup>95</sup> In 2015, the number of reference countries increased from six to nine through the addition of Belgium, Finland and Sweden.<sup>96</sup> The other countries are Denmark, the Netherlands, France, Germany, the UK and Austria. The countries were chosen because they are considered similar in terms of economic conditions and treatment traditions. Reference price reviews take place every 36 months.

Swissmedic handles marketing approval and the Federal Office of Public Health (FOPH) deals with reimbursement and pricing. When submitting an application to the FOPH, the pharmaceutical companies must present a positive recommendation from Swissmedic. Price is decided in the List of pharmaceutical specialities (SL).<sup>97</sup> Conditions for inclusion in the SL list include Swissmedic approving the pharmaceutical and it being deemed cost-effective. The cost analysis assesses international reference prices and there is also a therapeutic comparison to similar products. This involves a comparison with other products that already have subsidy status in Switzerland for the same or similar indication, and a comparison of treatment costs per day or total treatment cost. There is also an innovation bonus (for better efficacy, fewer side effects) of 1-20 per cent that may be applied in the therapeutic comparison.<sup>98</sup>

Prices are weighted with a 2/3 weighting according to the average for the international reference price and a 1/3 weighting for the national therapeutic comparison. There is a limit of five per cent if the national therapeutic comparison gives a higher value than the international reference price. In the absence of data on international reference prices (for example, if the pharmaceutical is not on the market in other countries), only the national therapeutic comparison is used.

The pharmacy margin is regulated and for prescription pharmaceuticals it is CHF 4-240 plus a percentage margin of 0-12 per cent that is added to the ex-factory price.

The price of generic pharmaceuticals should be at least 20 per cent lower than the price of the original. <sup>99</sup> An exception to this is generics with a small market share. Ceiling prices of generic pharmaceuticals are set differently depending on the sales of the original pharmaceutical four years before patent expiry. The price of the first subsequent product is set at least 10 per cent lower than the original's price if the original's sales value was below CHF 4 million. If the sales value of the original was

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<sup>95</sup> FOPH (2016a).

If ex-factory is not available then wholesaler or pharmacy price can be used. FOPH approximates margins according to: *Wholesaler margins have to be: Denmark: 6.5% of the pharmacy price, UK: 12.5% of the NHS-price*

*The Netherlands: 6.5% of the pharmacy price, Finland: 3% of the pharmacy price, Sweden: 2.7% of the pharmacy price*

<sup>96</sup> Interpharma, Price comparison with other countries.

<sup>97</sup> FOPH (2016b).

<sup>98</sup> FOPH (2016a).

<sup>99</sup> FOPH (2016a).

CHF 4-8 million, the price is set 20 per cent below that of the original. If the sales value of the original was CHF 8-16 million, the price is set 40 per cent below that of the original. If the sales volume was CHF 16-25 million, the price is set 50 per cent below that of the original. If the sales value exceeded CHF 25 million, the price of the subsequent product is set 60 per cent lower than the original.

The price of biosimilars is set to 25 per cent below the price of the original pharmaceutical.

Switzerland plans to introduce a reference price system for generic pharmaceuticals as well, but the time point of this measure has not been determined.

Private health insurance is compulsory for everyone living in Switzerland. The insurance cover includes the costs of pharmaceuticals obtained by prescription from a doctor. Co-payment amounts to CHF 300 annually. A further 10 per cent of the remaining cost amounting to maximum CHF 700 per year is added to this. If a generic alternative to the pharmaceutical is available but not selected, the patient's additional cost instead amounts to 20 per cent of the remaining cost of treatment.

#### Spain

Spain applies informal/supporting reference pricing based on lowest price. Reference price reviews take place every 12 months. Price information is collected at the ex-factory level.

Spain has implemented a far-reaching decentralisation of responsibility for healthcare. Since 2003, 17 regions have full budgetary responsibility for healthcare. The price in Spain must be below the lowest price available in the Euro zone countries in those cases where the cost-effectiveness is considered less favourable, or when a pharmaceutical is expected to have a large budgetary impact.<sup>100</sup>

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

Generic prescribing is encouraged in Spain. Substitution to the pharmaceutical with the lowest price in the group shall be implemented in pharmacies in all cases where prescriptions are prescribed with generic prescription.

During the first half of 2010, a discount of 7.5 per cent on original pharmaceuticals and 4 per cent on orphan pharmaceuticals was implemented. Official list prices should take this discount into account. At the same time, a 30 per cent price reduction was also implemented for generic pharmaceuticals.<sup>101</sup> A discount system

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<sup>100</sup> Ruggeri, K. and Nolte, E. (2013).

<sup>101</sup> Vogler et al (2011).

linked to the size of the pharmaceutical companies' investment in research and development in Spain is in place.

#### Greece

Greece adopted formal reference pricing in 2006. Prices (ex-factory) are based on an average of the lowest three prices of the other 27 EU countries. A price must be available in at least three countries for reference price calculation to be possible. As of 2016, a price review takes place twice a year, in May and November. Decisions on new products are made four times a year.

Pricing for generic pharmaceuticals has been amended several times in recent years. Since April 2016, the prices of generic pharmaceuticals have been linked to the price of original pharmaceuticals after patent expiry. Prior to this, they were linked to the price before or at the time of patent expiry.

The pricing mechanism for generic pharmaceuticals was amended in September 2015. Generic pharmaceuticals are priced 32.5 per cent lower than the original was prior to patent expiry - it was previously 20 per cent. Pharmaceuticals whose sales price does not exceed 4.5 euros and for which the patient's daily 24-hour dose does not cost more than 0.15 euros are exempt from mandatory price reduction for generic pharmaceuticals (as per January 2017).<sup>102</sup> From July 2017, the levels have been adjusted to a sales price of less than 1 euro and a daily price of less than 0.02 euro.

From August 2015, generic prescribing is once again mandatory. Previously, it was permitted to add a brand name to the prescription in addition to the generic prescription. Targets have been set for the proportion of generic pharmaceuticals a doctor should prescribe at the ATC4 level. If the target is not met, i.e. if a doctor prescribes originals at too great an extent, they may suffer financial consequences.

Prior to 2016, patients were responsible for the entire amount that exceeded the cheaper pharmaceutical (reference price) per therapeutic reference price group. Since 2016, patients and industry now share the cost. A limitation meaning that patients pay at most 20 euros extra per pharmaceutical has also been introduced. Previously, the limit was 50 euros extra per pharmaceutical.

The degree of subsidy is dependent on the disease: 100 per cent subsidy for pharmaceuticals for serious diseases and 90 per cent subsidy for pharmaceuticals for chronic conditions and pharmaceuticals for pensioners with low income. There is also a regular reimbursement level of 75 per cent.

#### Hungary

Hungary applies formal reference pricing using the lowest price of 31 countries (EU and EEA). Price information is collected at the ex-factory level. The intention is that

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<sup>102</sup> Previously, the sales levels for exemptions were higher, e.g. the limits were 12 euros and 0.40 euros per day 2015.

a reference price review for the products with the highest sales volume within the benefits scheme shall take place annually, but it is not yet implemented.

For generic pharmaceuticals in Hungary, the first subsequent product is priced at least 40 per cent below the price of the original. The second subsequent generic product is priced 20 per cent lower than the first subsequent product. The third sub-subsequent product is priced 10 per cent lower than the second subsequent product. The fourth through sixth subsequent product is priced five per cent lower than the preceding one. After this, subsequent products are only priced lower than the preceding one, without specification of minimum level. For biopharmaceuticals, the first subsequent product is priced 30 per cent lower than the price of the reference pharmaceutical, and the second and third product are priced 10 per cent lower than this.<sup>103</sup>

The degrees of subsidy are 85 per cent, 55 per cent and 25 per cent depending on therapeutic value and the severity of the disease. For some specific diseases, a stepped subsidy up to 100 per cent may apply.

#### Czech Republic

The Czech Republic applies formal reference pricing for both reimbursement and pricing. The reference countries are the entire EU, with the exception of Cyprus, Estonia, Malta, Luxembourg, Germany, Romania and Austria.<sup>104</sup> Greece no longer served as a reference country from 1 January 2018.

When deciding on reimbursement status, i.e. whether the pharmaceutical should be included in the benefits scheme, the lowest price of the reference countries is determined. If the lowest price is more than 20 per cent lower than the second lowest price, the average of the second and third lowest price is calculated. Price information is collected at the ex-factory level. When deciding on price, the average of the countries with the three lowest prices is calculated. The price is a ceiling price. Reference price reviews take place every 36 months.

Pharmaceuticals deemed to be "highly innovative" can receive temporary reimbursement status for a two-year period, which can be extended by one year. The pharmaceutical must exhibit a sufficiently high benefit and have already achieved reimbursement 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 32 per cent lower than the price of the original (30 percent for bio-pharmaceuticals). The same lowest price reduction is applied to the entire reference group.

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<sup>103</sup> Kawalec et al (2017).

<sup>104</sup> SÚKL (2017).

The co-payment is the difference between the fixed subsidised price and the sales price. The patient also pays a prescription dispensing fee of CZK 30 (approximately 1.20 euros).

From 2018, e-prescriptions are mandatory.

#### Slovakia

Slovakia applies formal reference pricing using prices from 27 countries. With the change in pricing introduced in 2008, the price in the six countries with the lowest price in Europe is compared. Since 2011, price is calculated as the average of three of the countries with the lowest price for a product.<sup>105</sup> Reference price reviews take place every 6 months. Price information is collected at the ex-factory level.

Pharmaceuticals classified as new and innovative are evaluated health economically with a ceiling price according to life years (QALY). The limit is set at the average annual work income in Slovakia for the previous two years.

The degree of subsidy is either 100 per cent or a partial amount.

Generic prescribing has been mandatory since 2011. At the time of dispensing, pharmacies are obliged to provide information on which pharmaceutical within the substitution group has the lowest price. For generic pharmaceuticals in Slovakia, the first subsequent product is priced at least 35 per cent lower than the original (at least 20 per cent for biosimilars).

#### Poland

Poland applies informal/supporting reference pricing using prices from 31 countries (EU and EFTA). Price information (ex-factory) is used in conjunction with the Economic Commission's price negotiations. Reference price reviews take place every 24 months. Poland has six countries that constitute a reference group for HTA assessments (Estonia, Latvia, Lithuania, Hungary, Croatia and Slovakia).

Every other month, the Ministry of Health publishes a list of pharmaceuticals that are subsidised. Depending on whether the length of treatment is more than or less than 30 days, the overall degree of subsidy for the pharmaceuticals in the benefits scheme is 50 or 70 per cent. The degree of subsidy is 100 per cent for certain diseases as well as for war veterans. Co-payments for certain pharmaceuticals (defined on the S-list) used by pensioners over 75 years of age were discontinued on 1 September 2016.

For generic pharmaceuticals, the subsequent pharmaceutical is priced at maximum 75 per cent of the reference price of the original. The first price decision applies for two years, and thereafter in three-year and five-year periods respectively.

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<sup>105</sup> Psenkova et al (2017).



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