International price comparison of pharmaceuticals 2017

– a volume based analysis of Swedish pharmaceutical prices and volumes relative to 19 other European countries.
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Preface

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

In this report, TLV presents the results of the analysis of price and volume data for the first quarter of 2014, 2015, 2016 and 2017 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 product-of-the-month system as per March 2017.

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

This report is part of TLV’s mandate to monitor developments in the Swedish pharmaceutical market from an international perspective and is the fourth annual report of its kind. This report was originally published in Swedish by TLV in Swedish December 2017, (TLV 2017j).

The analysis is based on prescription pharmaceuticals in outpatient care. TLV used price and sales data from IMS Health for the first quarters of 2014, 2015, 2016 and 2017. Price levels in Sweden are compared with 19 other European countries. The report is based on national list prices at an AIP (pharmacy purchase price) level. The pharmaceuticals have been divided into segments based on the conditions for competition in Sweden.

Price information is based on official list prices for outpatient care because it is only these prices that can be collected in a simple and standardised way. Thus, pricing for procured pharmaceuticals are not taken into account. Some countries have discounts of various kinds that are not reflected in list prices. Sweden also has managed entry agreements that reduce the cost or uncertainty for certain expensive pharmaceuticals. In some countries and for some specific pharmaceuticals, it can therefore be difficult to make direct comparisons. How the index develops over time relative to other countries is probably quite a good yardstick of how dynamic and adaptable the Swedish system is. Major focus in this report is therefore placed on analysing differences over time.

For pharmaceuticals in the segment ‘not exposed to competition’, the Swedish prices have declined relative to other countries since 2014. Between 2014 and 2015, Swedish relative prices fell due to several extensive reassessments for pharmaceuticals already included in the benefits scheme. Changes between 2016 and 2017 are relatively minor. Swedish prices have become marginally higher compared to other countries. Swedish prices fall among the nine countries with the highest price of the 20 countries compared. There are eight countries with higher prices compared with Sweden. This was the case in 2017 as well as 2016 and 2015. Calculated as a cross-sectional index, the 2017 price index is just over 100. On average, Swedish prices are thus in line with prices in other countries.

The segment ‘pharmaceuticals exposed to competition’ includes all pharmaceutical groups in the sample found in the product-of-the-month system in March 2017. In total, segment sales in Sweden were around SEK 3.9 billion (AIP running 12-month period through March 2017). This represents 19 percent of the sales in the sample. Sweden is found among the three countries with the lowest prices of the 20 countries compared.
Between 2014 and 2017, the Swedish prices decreased relative to all countries except Ireland and the Netherlands. During the study period, new products were continuously added to the ‘product-of-the-month system’ as competition arose when a pharmaceutical lost its patents. These products contributed to a fall in Swedish prices by nine index points compared with other countries. However, a deeper analysis of the new pharmaceuticals that entered the ‘product-of-the-month system’ shows that the Swedish system is poorer than that of other countries in relation to substances where the substitutability do not work.
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 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

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

**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.

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

**Cross-sectional price index** – the same product needs to be available in several countries to be included in any of the countries’ price indexes. The threshold, referred to as matching degree, has been set at 40 percent in those cases where cross-sectional indexes 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.

**Dosage form** – different 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 markups 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.
Generic name (INN) – 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.

International reference price (IRP, EPR, ERP) – pricing method where the price(s) of a pharmaceutical in one or more countries is taken into account 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.

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

Pharmacy purchase price (AIP) – pharmacy operator’s purchase price in SEK.

Pharmacy retail price (AUP) – pharmacy operator’s sales price in SEK.

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

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.

Original pharmaceutical – 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 for a number of years.

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.

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.
1 Introduction

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 instruction to TLV states, among other things, 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.1 This report is part of the ongoing work, and is the fourth report of its kind. This report was originally published in Swedish by TLV in Swedish December 2017.

The report describes how the prices of prescription pharmaceuticals in Sweden relate to 19 other European countries: Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Switzerland, Slovakia, Spain, United Kingdom, Czech Republic, Germany, Hungary and Austria. The comparison includes pharmaceuticals not exposed to competition2 as well as pharmaceuticals exposed to competition.3

The purpose is to analyse the Swedish prices compared to an international perspective. The dynamics in terms of changes to prices, volumes, exchange rates and product range that affected Swedish prices relative to other countries are also examined. The mandate does not include determining whether Swedish pharmaceutical prices are at the desired level, or suggest changes to potentially reach a desired level.

1.2 Outline

The report is arranged as follows. Section 2 contains a literature overview of the topic. Section 3 describes the underlying data and methodology. This is followed by a section on the pharmaceutical markets of the countries in the sample. Appendices 1 and 2 contain descriptions of the countries’ pharmaceutical pricing and reimbursement systems.

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1 According to § 2 of ordinance (2007:1206) with instructions for the Dental and Pharmaceutical Benefits Agency (TLV)

Swedish Code of Statutes 2007:1206 through SFS 2015:166

2 Segment pharmaceuticals not exposed to competition – includes products where competition between two different substitutable pharmaceuticals in Sweden has not arisen.

3 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.
The results are broken down by segment. The results for the segment ‘pharmaceuticals not exposed to competition’ follow in section 5. The results for the segment ‘pharmaceuticals exposed to competition’ are found in section 6.

The analysis uses the average exchange rate for the first quarter of 2017. The exception is the sensitivity analysis, which illustrates the effect of a non-constant exchange rate. As in previous studies (Brekke and Holmås 2012 and TLV’s last two reports), the sensitivity analysis looks at how the choice of various countries’ volume weights as base affect the price comparison. It is illustrated by switching to other countries’ volume weights for the segments ‘pharmaceuticals not exposed to competition’ and ‘pharmaceuticals exposed competition’.

This is followed by a discussion and continued work in section 8. Section 9 contains references, and the report concludes with Appendices 1 and 2 regarding the countries’ pricing and reimbursement systems.
2  Previous studies

In Sweden, TLV conducted three extensive analyses of Swedish pharmaceutical prices in comparison to other European countries in 2014, 2015 and 2016. This, the fourth report of its kind, follows a similar methodology.

A number of price comparison studies have been conducted in Norway, including those of Kurt Brekke at the Norwegian School of Economics. Particularly relevant in this regard are: Brekke et al. 2008, Brekke et al. 2011 and Brekke och Holmås 2012. The reports often address somewhat different issues. There are also variations in the surveyed segments, sub-populations of pharmaceuticals, time periods and comparison countries, making it difficult to compare the results of one report with those of another. A comparison could possibly indicate general correlations and relationships.

To evaluate the dynamics in Swedish prices compared to international ones, repeated studies must be conducted on the same population of pharmaceuticals in the same sample of countries. A more important factor is whether the analysis in an international price comparison is based on price and sales data, or if the analysis is only based on price data without any connection to actual pharmaceutical use.

2.1  Price and volume analyses

Brekke and Holmås 2012\textsuperscript{4} studied how different countries’ volume weighting affects the price comparison. They examined the extent to which Swedish pharmaceutical consumption/Swedish volume weights affect the price index from a Norwegian perspective. The data set was made up of the prices of 73 substances without generic competition in all countries and their sales data from Sweden and Norway. Brekke and Holmås showed that changing the base for weighting from Norwegian to Swedish consumption influenced the index level. Countries with a relatively high index become higher, i.e. became relatively more expensive compared to Sweden, and countries with a relatively low index became lower (closer to zero), i.e. cheaper relative to Sweden. The sensitivity analysis of this study compares the change of base country from Swedish to another country’s weights, which was also done in TLV’s previous international price comparisons.

**TLV’s international price comparison 2014**

TLV’s study from 2014\textsuperscript{5} compared the price level in Sweden with 15 other European countries divided into three segments. The analysis was based on price and sales data from IMS. The results of the analysis of the segment ‘pharmaceuticals not exposed to competition’ showed that Swedish pharmaceutical prices were slightly higher than in several of the comparison countries. Of the 15 comparison countries, Swedish prices were among the five highest. The analysis showed that a relatively


\textsuperscript{5} TLV (2014a).
small number of substances accounted for a large part of this price difference. It also showed that older pharmaceuticals introduced up to and including 1998 had prices that were in line with other countries. Prices were slightly higher in Sweden in relative terms for pharmaceuticals introduced after 1998. Previous reports, which are not entirely comparable, indicated that the prices of older pharmaceuticals not exposed to competition had been higher in Sweden than in other countries. In addition, TLV studied two other segments in 2014, namely pharmaceuticals exposed to competition that are not included in the product-of-the-month system, and substitutable pharmaceuticals included in the product-of-the-month system. The analysis showed that by international standards Sweden exhibited a low price level for pharmaceuticals exposed to competition, i.e. the part of the pharmaceutical segment included in the product-of-the-month system. Sweden, along with Denmark and the Netherlands, constituted the group of countries that exhibited a significantly lower price in this segment compared to the other 13 countries.

TLV’s international price comparison 2015

TLV’s study from 2015\(^6\) compared the price level in Sweden with 19 other European countries based on price and sales statistics from IMS. The report was based on national list prices at AIP level and pharmaceuticals were grouped based on the conditions for competition. The study found that TLV’s reassessments of pharmaceuticals already within the benefits scheme are important for pharmaceuticals not exposed to competition. Changes in prices for pharmaceuticals that had been exposed to an authority intervention (either reassessment or the 15-year rule) had contributed the most to lowering Swedish relative prices. For the segment ‘pharmaceuticals exposed to competition’ (including all pharmaceutical groups in the sample that were included in the product-of-the-month list in March 2015), the study showed that Sweden was among the three countries with the lowest prices in the sample along with Denmark and the Netherlands. Between 2014 and 2015, the difference in prices between the countries decreased slightly, but there were still major differences. Above all, it was in countries that in 2014 were considerably more expensive than Sweden where prices had fallen the most. Large price differences should even out over time since several countries apply some degree of international reference pricing and thus over time will be affected by other countries’ prices. An in-depth analysis within the product-of-the-month system also showed that the Swedish system works best relative to other countries when sales volumes are high.

TLV’s international price comparison 2016

TLV’s study\(^7\) based on 2016 data used the same study procedure to analyse prices and volumes in an international perspective as the study based on 2015 data\(^8\). The report was published in both Swedish and English\(^9\).

The analysis showed that the differences in prices between the countries decreased slightly for pharmaceuticals exposed to competition between 2014 and 2015, but increased again between 2015 and 2016, strengthening Sweden’s position in the group.

\(^6\) TLV (2015).
\(^7\) TLV (2017a).
\(^8\) TLV (2016a).
\(^9\) TLV (2017b).
of countries with the lowest prices in Europe. The analysis also showed that the Swedish substitution system quickly reduces pharmaceutical prices. The price drops sharply immediately after competition arises. When it comes to pharmaceuticals not exposed to competition, a group predominantly made up of patented original pharmaceuticals, the Swedish prices landed among the eight countries with the highest price of the 20 countries compared for both 2015 and 2016. On average, Swedish prices were in line with prices in other countries.

### 2.2 Price comparisons lack volume data

Two studies analysed price differences of cancer medicines in European countries. A 2016 study by van Harten et al.\(^ \text{10}\) analysing prices in 15 European countries found that the list prices of cancer medicines could vary widely and be up to 92 percent lower than the highest reported price, and that actual prices could be up to 58 percent lower. A 2015 study by Vogler et al.\(^ \text{11}\) analysing prices of 30 cancer medicines in 16 European countries plus Australia and New Zealand found that the price differences of 31 different cancer medicines, measured as highest to lowest list price, could vary between 28 percent and 388 percent. Among other things, the study found that Greek prices were low and that the price levels in Sweden, Switzerland and Germany were high.

Vogler et al. discussed the limitations of using list prices as compared to actual prices. The authors write that they are aware that discount agreements and specially arranged adoption processes have increased in number and have been signed for cancer medicines, but analysis of the level is not possible due to lack of transparency. However, one aspect the authors fail to mention is how use of the 30 cancer medicines compare.

In order for a price analysis to be as fair as possible, the pharmaceutical price data must be supplemented with volume data on actual use as well as information on whether use is prescription-based or not. This type of analysis, which is slightly more complex, makes it possible to better evaluate how costly use is in Sweden and the patterns for actual use.

By all accounts, Sweden has relatively high prices for many of the cancer medicines listed in Vogler et al. However, the study only addresses the magnitude of the differences in list price and not factors such as actual use and whether the pharmaceuticals are primarily used within outpatient or inpatient care. The pharmaceuticals for which Sweden has the highest prices are consistently used primarily in inpatient care. The prices applied to inpatient care differ from those in outpatient care, where TLV is able to influence prices. Due to procurement processes, inpatient care prices are generally lower than prices for equivalent products in outpatient care. The official list prices in outpatient care have little significance for these pharmaceuticals. In addition, prices vary between Swedish county councils, making it difficult to provide an overall picture.

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In TLV’s price comparisons from 2012, 2014, 2015, 2016 and in this report, price differences are weighted according to the actual use in Sweden. The analyses for 2015 and 2016 also included a sensitivity analysis on the effect of replacing the base country of the volume weighting. This method makes it possible to evaluate the impact of differences in prices based on Swedish consumption. But even this comparison is limited to only analysing pharmaceuticals that are prescribed in outpatient care and for which there are list prices and use in other countries. In cases where there are hidden discounts or different variants of rebate agreements, or where procurement takes place within the framework of inpatient care, the prices are likely to be lower than the list price.

2.3 Analysis of choice of method for index calculation

Wouters and Kanavos\(^\text{12}\) analysed the different weighting methods used in pharmaceutical price comparisons. Based on 2013 prices and volume data for 110 substances exposed to competition, the authors calculated the price index for seven countries with similar income levels. Wouters and Kanavos calculated the unweighted index, Paasche index, Laspeyres index and Fisher index. They also analysed adjustment based on purchasing power and exchange rate. They found that Sweden and Denmark showed the lowest price level at both the distribution level and the retail level, i.e. the pharmacy purchase prices, for these pharmaceuticals. France and Italy had the highest index in most of the weighted analyses. The authors found that the calculated Paasche index was consistently lower than the Laspeyres index.

3 Data and methodology

3.1 Different segments depending on the conditions for competition

The pharmaceuticals have been divided into segments based on the conditions for competition in Sweden.

These segments are:

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

The segment **pharmaceuticals not exposed to competition** includes products where competition between at least two different substitutable pharmaceuticals in Sweden has not arisen. The segment includes both products that are patented and products whose patent protection has expired, but for which no competition between two substitutable pharmaceuticals has arisen. This segment also includes biosimilars as they are not directly substitutable with the reference product. These pharmaceuticals are included in the same segment because TLV’s ability to influence the price is the same. However, competitive conditions may differ between the countries in the comparison.

The segment **pharmaceuticals exposed to competition (in the product-of-the-month system)** includes all pharmaceuticals available as generic substitutes within the product-of-the-month as per March 2017. TLV regulation 2009:4\(^\text{13}\) specifies which pharmaceuticals are eligible for the product-of-the-month system.

3.2 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, IMS was tasked with delivering data for 200 products within the ‘protected pharmaceuticals’ segment, 180 products 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.

The 2017 segmentation is similar to that of the 2015 and 2016 analysis, but differs from the 2014 analysis. The data for the first quarters of all four years are therefore

\(^{13}\) See TLV regulations at [http://www.tlv.se/tlv/regelverk/foreskrifter](http://www.tlv.se/tlv/regelverk/foreskrifter) for regulation TLVFS 2009:4 ‘Pricing of substitutable pharmaceuticals and replacement of pharmaceuticals, etc.’ as well as the amendments to the regulation.
analysed and presented. In other words, all analyses that compare with previous years refer to new, analysed data and not analysis presented in previous reports.

Price indexes 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.

### 3.3 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 done in different ways, with different consequences for precision and for how many countries include the pharmaceuticals 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.

In Sweden, medicines are normally provided 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. To correct for this, the price has been calculated as cost per dose for a particular substance, dosage form and strength. This makes it possible to compare different pack sizes with each other, making the price indexes 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 amount of time between dispensing, the greater the probability that larger packs 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

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14 IMS describes price data as *ex-wholesaler price or price to chemist per pack*. 
problem with this type of price comparison is difficulties qualifying which pharmaceuticals belong to a specific therapy group, and that treatment traditions may differ between countries.

3.3.1 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 percent of the Swedish, 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 2017 and total number of inhabitants in 2017 in the respective country are used for the calculation.

3.3.2 Descriptive statistics

The collective Swedish sales value of the pharmaceuticals included in the sample is described in the following table. In total, Swedish sales in the sample amounted to SEK 20.6 billion, which is approximately 90 percent of the total sales of pharmaceuticals in the benefits scheme in Sweden. Selection is based on the main products in each segment and is thus not random. It is therefore not possible to generalise the price indexes for the selection to the total market. Products not included in the sample have on average a lower price per pack in Sweden. The pricing mechanism of these pharmaceuticals may differ from the pharmaceuticals in the sample, making it difficult to draw far-reaching conclusions about price level.

Table 1. Sales of pharmaceuticals at the AIP level that are part of the sample for different segments, MSEK, rolling 12 months

<table>
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<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not exposed to competition</td>
<td>16,710</td>
<td>16,585</td>
<td>15,053</td>
<td>13,317</td>
</tr>
<tr>
<td>Exposed to competition</td>
<td>3,880</td>
<td>3,803</td>
<td>4,067</td>
<td>4,164</td>
</tr>
<tr>
<td>Total in the sample</td>
<td>20,591</td>
<td>20,388</td>
<td>19,121</td>
<td>17,481</td>
</tr>
<tr>
<td>Total sales of pharmaceuticals</td>
<td>22,936</td>
<td>21,984</td>
<td>20,141</td>
<td>16,168</td>
</tr>
<tr>
<td>in the benefits scheme in Swe-</td>
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<tr>
<td>den</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of sales in sample</td>
<td>90%</td>
<td>93%</td>
<td>95%</td>
<td>91%</td>
</tr>
<tr>
<td>in relation to Swedish sales</td>
<td></td>
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</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.

3.4 Sales volumes and weighting

It is common practice to weight the volume of various product prices in a price index. 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:
\[ I_p = \frac{p_1^1w_1 + p_1^2w_2 + \cdots + p_n^1w_n}{p_1^0w_1 + p_2^0w_2 + \cdots + p_n^0w_n} \times 100 \]

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:

\[ L_p = \frac{p_1^Uq_1^S + p_2^Uq_2^S + \cdots + p_n^Uq_n^S}{p_1^Sq_1^S + p_2^Sq_2^S + \cdots + p_n^Sq_n^S} \times 100 \]

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, 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. In this study, however, the average exchange rate for the first quarter of 2017 is consistently applied. This also applies to the index data reported for 2014, 2015 and 2016. The only exception is in the sensitivity analysis, which shows the effect of not keeping the exchange rate constant.

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 in section 7.2, which shows the effect of using other countries’ volume weights.

3.4.1 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 one of the compared countries 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 indexes. The threshold, referred to as matching degree, has been set at 40 percent in those cases where cross-sectional indexes 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 number of pharmaceuticals that 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 maximizes 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 indexes, thereby capturing all pharmaceuticals that match with each individual country. The value that these pharmaceuticals represents, compared to the total Swedish sales in the sample, varies between countries.

### 3.5 Exchange rates

One factor that influences prices over time is the exchange rate. Exchange rate fluctuations affect relative prices compared to other countries. If the currency of a country grows stronger, prices in other countries will seem to have dropped, even if they are nominally unchanged in the respective country’s currency. All things being equal, a stronger Swedish Krona means that Swedish prices appear to be higher compared to when the Krona is weak.

Throughout the report, the analysis uses the average exchange rate for the first quarter of 2017. This also applies to the index data reported for other years. The
only exception is the sensitivity analysis, which illustrates the effect of a non-constant exchange rate. The average exchange rates relative to SEK for 2014 - 2017 are found in the table below.

**Table 2. Average exchange rate and relative change compared to SEK**

<table>
<thead>
<tr>
<th></th>
<th>Quarter 1 2014</th>
<th>Quarter 1 2015</th>
<th>Quarter 1 2016</th>
<th>Quarter 1 2017</th>
<th>Relative change, Q1 2017 – Q1 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEK</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0.0%</td>
</tr>
<tr>
<td>EUR</td>
<td>8.86</td>
<td>9.39</td>
<td>9.33</td>
<td>9.51</td>
<td>1.9%</td>
</tr>
<tr>
<td>CZK</td>
<td>0.32</td>
<td>0.34</td>
<td>0.35</td>
<td>0.35</td>
<td>1.9%</td>
</tr>
<tr>
<td>DKK</td>
<td>1.19</td>
<td>1.26</td>
<td>1.25</td>
<td>1.28</td>
<td>2.2%</td>
</tr>
<tr>
<td>GBP</td>
<td>10.70</td>
<td>12.63</td>
<td>12.11</td>
<td>11.05</td>
<td>-8.8%</td>
</tr>
<tr>
<td>HUF</td>
<td>0.03</td>
<td>0.03</td>
<td>0.03</td>
<td>0.03</td>
<td>2.8%</td>
</tr>
<tr>
<td>NOK</td>
<td>1.06</td>
<td>1.08</td>
<td>0.98</td>
<td>1.06</td>
<td>8.0%</td>
</tr>
<tr>
<td>PLN</td>
<td>2.12</td>
<td>2.24</td>
<td>2.14</td>
<td>2.20</td>
<td>2.9%</td>
</tr>
<tr>
<td>CHF</td>
<td>7.24</td>
<td>8.76</td>
<td>8.52</td>
<td>8.89</td>
<td>4.3%</td>
</tr>
</tbody>
</table>

Note: A higher number and a positive change mean that the Swedish currency has weakened against the local currency.

Note: Swiss Franc (CHF), Danish Krone (DKK), Euro (EUR), British Pound (GBP), Norwegian Krone (NOK), Czech Koruna (CZK), Hungarian Forint (HUF), Polish Zloty (PLN) and US Dollar (USD)

Source: Riksbank, NASDAQ OMX Stockholm AB and TLV analysis.

The following figure illustrates the relative exchange rate change of the Swedish Krona for the period 2014 - 2017. The period was occasionally characterised by major movements in the foreign exchange market. The Swiss Franc, British Pound and US Dollar grew significantly stronger against the Swedish Krona at the end of 2014. While the British Pound has dropped back since 2016, the US Dollar and Swiss Franc have remained at a high level against the Swedish Krona. The Euro and currencies denominated against the Euro (e.g. Danish Krone) show relatively small changes. The Norwegian Krone grew stronger against the Swedish Krona between the first quarter of 2016 and the first quarter of 2017.

**Figure 1. Relative exchange rate change compared to SEK during the period January 2013–September 2017, per month. 0 = January 2014.**
Note: Broken axis: The two shaded areas illustrate the time period examined in the previous international price comparison reports from TLV and the time period that is the subject of this study. Since the analysis is based on quarterly data, the average exchange rate for the period January–March is used for relevant currencies. Source: Riksbank, NASDAQ OMX Stockholm AB and TLV analysis.
4  The pharmaceuticals market

4.1  Market overview

The purpose of the sections on market overview, pricing models and facts about the countries in the study (Appendices 1 and 2) 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 are more diverse. This may relate to transparency regarding list prices and whether or not discount systems are institutionalised and included in pharmacy purchase prices, or whether 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 7,224 billion, calculated as the price from the manufacturer.\(^{15}\) North America dominates the pharmaceutical market and represents about 49 percent of the world market. Europe in its broadest sense represents about 22 percent.\(^{16}\) Africa, Asia and Australia together account for just over 16 percent, Japan represents just over 8 percent of the world market and Latin America just over 4 percent.

For the 20 countries in the study, the total sales amount to SEK 1,660 billion at the AIP level for both outpatient and inpatient care. The total outpatient sales for the countries amount to SEK 1,045 billion for the period, accounting for 63 percent of the total sales value.\(^{17}\) The sales value of the pharmaceuticals included in the analysis amounts to SEK 738 billion, which represents 71 percent of the total outpatient sales for the countries in the sample. The difference compared to total sales is attributable to the limitation that the product needs to be registered for sales on the Swedish market and not just be registered in another country to be included in the analysis.

The total population of the 20 countries in the study amounts to about 484 million inhabitants. The five largest countries in terms of population (Germany, France, United Kingdom, Italy and Spain) together account for almost 67 percent of the population base. At the same time, these five countries account for about 70 percent of the 20 countries’ total sales in the analysis at the AIP level. Sweden’s share of the population is 2 percent, and its share of the total sales is just over 3 percent.

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\(^{15}\) This means that costs for transport from the factory plus taxes and markups will be added. EFPIA indicates € 763,101 million for 2016. Conversion to SEK at average exchange rate (9.47) from Swedish Riksbank.

\(^{16}\) EFPIA (2017).

\(^{17}\) Measured as units, total sales for outpatient and inpatient care in the 20 countries amounted to 825 billion units, with 405 billion units attributable to outpatient care and 420 billion units attributable to inpatient care.
4.2 Outpatient and inpatient care

Caution should be exercised when comparing data for outpatient care only. In some countries, some pharmaceuticals are largely managed within inpatient care, while in Sweden they are largely managed within outpatient care. The choice of pharmaceutical management, i.e. by prescription in outpatient care or at a hospital with inpatient care, makes it difficult to draw far-reaching conclusions using this type of comparison without having knowledge about specific national conditions related to pharmaceutical management.

The figure below shows the percentage of outpatient and inpatient management by sales value. On average, these 19 countries manage 65 percent of the total sales within the context of outpatient care. Denmark, Italy, Spain and the United Kingdom are the countries that have a relatively small sales value within outpatient care and a significantly high relative percentage that is managed within inpatient care. In Sweden, approximately 75 percent is managed within outpatient care, i.e. management through issuing of prescriptions, and 25 percent is managed within inpatient care.

Figure 2. Outpatient and inpatient management of pharmaceuticals, based on sales over rolling 12 months, through March 2017.

The following figure shows outpatient and inpatient pharmaceutical sales per inhabitant in Europe. The average amounts to SEK 3,381.18 The total sales value per inhabitant is highest in Switzerland (SEK 6,266 per inhabitant), followed by Austria (SEK 4,400 per inhabitant). Sweden has the twelfth highest sales of all countries with about SEK 3,335 per inhabitant in total sales value, with SEK 2,491 attributable to outpatient care and 844 to inpatient care.

18 Represents the average for 19 of the countries in the analysis. Excluding Greece, since there is no inpatient care data.
Based on total sales value per inhabitant, our Nordic neighbours Denmark, Norway and Finland have slightly higher costs compared to Sweden.

Figure 3. Outpatient and inpatient sales of pharmaceuticals per capita, based on sales over rolling 12 months, through March 2017.

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

There may be differences 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 outpatient or inpatient care. Another difference could be variations in drug therapies, which could mean that an affliction 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 have a price in the comparison country.
4.3 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 a number of reference countries\(^{19}\) or to base pricing on appraised values or profitability.

<table>
<thead>
<tr>
<th>Table 3. How are pharmaceutical prices set?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Alternative method to international reference pricing</td>
</tr>
<tr>
<td>a) Value-based pricing</td>
</tr>
<tr>
<td>b) Indirect price control by assessing value and profitability</td>
</tr>
<tr>
<td>c) Free pricing</td>
</tr>
<tr>
<td>2 International reference pricing</td>
</tr>
<tr>
<td>a) Formal</td>
</tr>
<tr>
<td>b) Informal/supporting in combination with another method (e.g. assessment of benefit or value)</td>
</tr>
</tbody>
</table>

Source: TLV analysis.

Reference pricing 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 taken into account 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, the method is described, for example that the countries must be similar in terms of certain characteristics such as economy or geographic proximity. In most cases, however, the reasoning behind why certain countries are defined as reference countries is not clearly motivated.

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 33.3 percent (1/3 countries) to 3.2 percent (1/31 countries). 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 in terms of whether prices are only decreased or if they can also be increased 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 the 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. Other countries with reference pricing have not specifically stated whether price is

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\(^{19}\) This is referred to as IRP = international reference pricing. The abbreviation EPR = external reference pricing is sometimes used instead. International and external reference pricing are the same thing. 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.
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 three to sixty months after a price decision.

**Table 4. Pricing models for the 20 countries included in the survey**

<table>
<thead>
<tr>
<th>Country</th>
<th>Pricing model (pharmaceuticals not exposed to competition)</th>
<th># of countries</th>
<th>Reference countries</th>
<th>Method</th>
<th>Time until price readjustment (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>No IRP. Competition/ price report</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>No IRP. Indirect price control</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sweden</td>
<td>No IRP. VBP</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Greece</td>
<td>IRP, formal</td>
<td>27</td>
<td>Rest of EU</td>
<td>Average of 3 lowest</td>
<td>3/6</td>
</tr>
<tr>
<td>Ireland</td>
<td>IRP, formal</td>
<td>14</td>
<td>Austria, Belgium, Denmark, Spain, Finland, France, Netherlands, United Kingdom, Sweden, Portugal, Luxembourg, Greece and Italy</td>
<td>Average</td>
<td>12</td>
</tr>
<tr>
<td>Netherlands</td>
<td>IRP, formal</td>
<td>4</td>
<td>Belgium, Germany, France, United Kingdom</td>
<td>Average</td>
<td>6</td>
</tr>
<tr>
<td>Norway</td>
<td>IRP, formal</td>
<td>9</td>
<td>Belgium, Denmark, Finland, Ireland, Netherlands, United Kingdom, Sweden, Germany and Austria</td>
<td>Average of 3 lowest</td>
<td>12</td>
</tr>
<tr>
<td>Portugal</td>
<td>IRP, formal</td>
<td>3</td>
<td>Spain, France, Slovenia</td>
<td>Average</td>
<td>12</td>
</tr>
<tr>
<td>Switzerland</td>
<td>IRP, formal</td>
<td>9</td>
<td>Belgium, Austria, Germany, Denmark, Finland, France, Netherlands, Sweden and United Kingdom</td>
<td>Average</td>
<td>36</td>
</tr>
<tr>
<td>Slovakia</td>
<td>IRP, formal</td>
<td>27</td>
<td>Rest of EU</td>
<td>Average of 3 lowest</td>
<td>6</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>IRP, formal</td>
<td>*28/19</td>
<td>Rest of EU for reimbursement decision. For price decision: Belgium, Germany, Spain, Finland, France, Netherlands, Croatia, Ireland, Italy, Lithuania, Latvia, Hungary, Poland, Portugal, Greece, Slovakia, Slovenia, Sweden, United Kingdom</td>
<td>Average of 3 lowest</td>
<td>36</td>
</tr>
<tr>
<td>Hungary</td>
<td>IRP, formal</td>
<td>31</td>
<td>EU and EEA</td>
<td>Not determined/ lowest price</td>
<td>24</td>
</tr>
<tr>
<td>Austria</td>
<td>IRP, formal</td>
<td>27</td>
<td>Rest of EU</td>
<td>Average</td>
<td>-</td>
</tr>
<tr>
<td>Belgium</td>
<td>IRP, informal/supporting</td>
<td>27</td>
<td>Rest of EU</td>
<td>Average</td>
<td>-</td>
</tr>
<tr>
<td>Finland</td>
<td>IRP, informal/supporting</td>
<td>29</td>
<td>EEA (Rest of EU + Norway and Iceland)</td>
<td>Not determined/ average</td>
<td>60</td>
</tr>
<tr>
<td>France</td>
<td>IRP, informal/supporting</td>
<td>4</td>
<td>United Kingdom, Italy, Spain and Germany</td>
<td>Average/ “close” price</td>
<td>60</td>
</tr>
<tr>
<td>Italy</td>
<td>IRP, informal/supporting</td>
<td>24</td>
<td>Other countries in the EURIPID database</td>
<td>Not determined/ lowest price</td>
<td>24</td>
</tr>
<tr>
<td>Poland</td>
<td>IRP, informal/supporting</td>
<td>31</td>
<td>EU and EFTA</td>
<td>Not determined/ average</td>
<td>24</td>
</tr>
<tr>
<td>Spain</td>
<td>IRP, informal/supporting</td>
<td>*18/3</td>
<td>Euro countries, but with greater emphasis on three countries – France, Italy and Portugal</td>
<td>Lowest price</td>
<td>12</td>
</tr>
<tr>
<td>Germany</td>
<td>IRP, informal/supporting</td>
<td>15</td>
<td>Austria, Belgium, Cyprus, Denmark, Greece, Spain, Finland, France, Ireland, Italy, Netherlands, Portugal, Sweden, Slovakia, United Kingdom</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Note: The list only regards outpatient care and primarily pharmaceuticals not exposed to competition. Some countries apply the same system, while other countries apply different systems depending on competition with a specific substance. Refer to Appendix 2 for a description of the pricing systems used by the different countries.

Source: TLV analysis.
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 do not utilise international reference pricing. Value-based pricing is used in Sweden. 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.

The system for generic substitution coupled with the lowest price for a particular product during a certain time period is found, for example in Denmark, which has a two-week period; in Sweden with the product-of-the-month for a one-month period; in the Netherlands, where a product can be the one preferred for sale for a period of three, six, twelve or 24 months; and in Finland, with a system where the ‘product-of-the-month’ period is three months. In Finland, the price can vary during this period. The systems for generic substitution in these countries differ, but the basic idea is the same, i.e. 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 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 “sidoöverenskommelser” 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 arranged introduction.

Portugal, Germany\(^\text{20}\) and Spain are examples of countries with general discount systems that are not likely to be seen in list prices.\(^\text{21}\) Lack of complete information on any 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

\(^{20}\) KBV (2016).

products between 2014, 2015, 2016 and 2017 is a clear advantage. Assuming that any discounts are at about the same level from one year to the next gives a relative comparison a reasonably good picture 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.
5 Results: pharmaceuticals not exposed to competition

This section describes Swedish prices for the segment of pharmaceuticals that are not exposed to competition and are not included in the product-of-the-month system. In total, segment sales in Sweden were around SEK 16.7 billion (AIP running 12-month period through March 2017). This represents 81 percent of the sales in the sample for this survey.

Since 2014, Swedish prices have decreased relative to other countries. Between 2014 and 2015, Swedish relative prices fell due to several extensive reassessments for pharmaceuticals already included in the benefits scheme. Changes between 2016 and 2017 are relatively minor. Swedish prices have become marginally higher compared to other countries. The Swedish prices fall among the nine countries with the highest price of the 20 countries compared. There are eight countries with higher prices compared with Sweden. This was the case in 2017 as well as 2016 and 2015. Calculated as a cross-sectional index, the 2017 price index is just over 100. On average, Swedish prices are thus in line with prices in other countries. The exchange rate is held constant to the average first quarter in 2017 in all of the analyses in this section.

5.1 Description of pharmaceuticals not exposed to competition

This section describes pharmaceuticals not exposed to competition and not included in the product-of-the-month system. This segment includes patented pharmaceuticals as well as pharmaceuticals without patent for which no competition has arisen in the product-of-the-month system. Within this segment, there may be competition between different substances, but not through mandatory substitution at the pharmacy like in the product-of-the-month system. This segment includes the pharmaceuticals launched most recently and those with the highest cost. Price comparisons are based on products available in Sweden. If a country uses a different product, that product is not included in the price comparison.

The pharmaceuticals that are part of the segment ‘not exposed to competition’ had sales of SEK 16.7 billion AIP over twelve months up to and including March 2017. Table 5 lists the sales value per ATC1 code. ATC code L, which includes popular anti-cancer and anti-rheumatic medicines, is the absolute largest group of pharmaceuticals in terms of sales value. These pharmaceuticals had sales of almost SEK 5.3 billion over twelve months up to and including March 2017, which corresponds to about one-third of the total sales in this segment.

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22 See Terms and concepts for a listing of the 14 main groups of the ATC system.
Table 5. Sales of pharmaceuticals at the AIP level that are part of the segment not exposed to competition per ATC code, MSEK, rolling 12 months

<table>
<thead>
<tr>
<th>ATC group, segment not exposed to competition</th>
<th>Sales, March 2017 (AIP)</th>
<th>Percentage of sales</th>
<th>Diff compared to 2014 MSEK</th>
<th>Change (%)</th>
<th>Contribution to total change</th>
<th>Contribution per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Alimentary tract and metabolism</td>
<td>1,699</td>
<td>10%</td>
<td>374</td>
<td>28.2%</td>
<td>3.1%</td>
<td>1.0%</td>
</tr>
<tr>
<td>B Blood and blood-forming organs</td>
<td>2,161</td>
<td>13%</td>
<td>789</td>
<td>57.5%</td>
<td>6.5%</td>
<td>2.1%</td>
</tr>
<tr>
<td>C Cardiovascular system</td>
<td>622</td>
<td>4%</td>
<td>99</td>
<td>18.9%</td>
<td>0.8%</td>
<td>0.3%</td>
</tr>
<tr>
<td>D Dermatological medicines</td>
<td>208</td>
<td>1%</td>
<td>22</td>
<td>11.8%</td>
<td>0.2%</td>
<td>0.1%</td>
</tr>
<tr>
<td>G Genitourinary system and reproductive hormones</td>
<td>579</td>
<td>3%</td>
<td>85</td>
<td>17.1%</td>
<td>0.7%</td>
<td>0.2%</td>
</tr>
<tr>
<td>H Systemic hormone preparations, excluding sex hormones and insulins</td>
<td>657</td>
<td>4%</td>
<td>35</td>
<td>5.7%</td>
<td>0.3%</td>
<td>0.1%</td>
</tr>
<tr>
<td>J Antimicrobials for systemic use</td>
<td>1,810</td>
<td>11%</td>
<td>1,142</td>
<td>171.1%</td>
<td>9.4%</td>
<td>3.0%</td>
</tr>
<tr>
<td>L Antineoplastic and immunomodulating agents</td>
<td>5,317</td>
<td>32%</td>
<td>1,577</td>
<td>42.2%</td>
<td>12.9%</td>
<td>4.1%</td>
</tr>
<tr>
<td>M Musculoskeletal system</td>
<td>173</td>
<td>1%</td>
<td>47</td>
<td>37.7%</td>
<td>0.4%</td>
<td>0.1%</td>
</tr>
<tr>
<td>N Nervous system</td>
<td>1,906</td>
<td>11%</td>
<td>625</td>
<td>48.8%</td>
<td>5.1%</td>
<td>1.7%</td>
</tr>
<tr>
<td>P Antiparasitic products, insecticides and repellents</td>
<td>12</td>
<td>0%</td>
<td>-2</td>
<td>-11.6%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>R Respiratory system</td>
<td>1,223</td>
<td>7%</td>
<td>-348</td>
<td>-22.1%</td>
<td>-2.8%</td>
<td>-1.0%</td>
</tr>
<tr>
<td>S Sensory organs</td>
<td>307</td>
<td>2%</td>
<td>40</td>
<td>15.0%</td>
<td>0.3%</td>
<td>0.1%</td>
</tr>
<tr>
<td>V Other</td>
<td>35</td>
<td>0%</td>
<td>9</td>
<td>33.0%</td>
<td>0.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Total</td>
<td>16,710</td>
<td>100%</td>
<td>4,495</td>
<td>36.8%</td>
<td>36.8%</td>
<td>11.0%</td>
</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.

The areas alimentary tract (A), blood (B), antimicrobials (J) and nervous system (N) each have sales of about SEK 2 billion. Sales within respiratory system (R) are also relatively high at SEK 1.2 billion. In the further analysis, the ATC codes with lower sales are grouped into the category ‘other’, which is made up of ATC1 codes C, D, G, H, P, S and V.

5.1.1 Top ten substances not exposed to competition

This section describes differences between use in Sweden and in other countries. The analysis is based on products available in Sweden. Any product that is used in another country but is not available in Sweden is not included in the analysis.

table 6 shows the ten substances in outpatient care that have the highest sales value in other countries (abroad). These substances account for about 29 percent of sales abroad. The corresponding percentage for these pharmaceuticals in Sweden is about 26 percent of domestic sales. Although the percentage is similar, the distribution differs in many cases. The big sellers abroad are the blood thinner rivaroxaban (B01A) and the asthma medicine salmeterol, fluticasone (R03A). These medicines make up a small percentage of the sales value in Sweden, but this is since other similar medicines are used. In Sweden, apixaban (B01A) is used more extensively than rivaroxaban, and budesonide, formoterol is used more extensively than salmeterol, fluticasone in the treatment of asthma.
Table 6. The ten substances within the segment ‘not exposed to competition’ with the highest sales volume abroad, running 12-month period through March 2017.

<table>
<thead>
<tr>
<th>ATC4</th>
<th>Substance</th>
<th>Percentage of sales value abroad</th>
<th>Percentage of sales volume abroad</th>
<th>Percentage of sales value Sweden</th>
<th>Percentage of sales volume Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>B01A</td>
<td>Rivaroxaban</td>
<td>4.7%</td>
<td>1.2%</td>
<td>1.9%</td>
<td>0.6%</td>
</tr>
<tr>
<td>R03A</td>
<td>Salmeterol, fluticasone</td>
<td>3.1%</td>
<td>3.8%</td>
<td>0.8%</td>
<td>1.0%</td>
</tr>
<tr>
<td>L04A</td>
<td>Etanercept</td>
<td>3.1%</td>
<td>0.0%</td>
<td>6.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>R03A</td>
<td>Budesonide, formoterol</td>
<td>2.8%</td>
<td>4.3%</td>
<td>3.6%</td>
<td>6.0%</td>
</tr>
<tr>
<td>L04A</td>
<td>Adalimumab</td>
<td>2.6%</td>
<td>0.0%</td>
<td>3.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>B01A</td>
<td>Apixaban</td>
<td>2.6%</td>
<td>1.3%</td>
<td>3.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>A10A</td>
<td>Insulin, glargine</td>
<td>2.2%</td>
<td>0.4%</td>
<td>1.7%</td>
<td>0.3%</td>
</tr>
<tr>
<td>C10A</td>
<td>Rosuvastatin</td>
<td>2.1%</td>
<td>1.4%</td>
<td>1.1%</td>
<td>0.8%</td>
</tr>
<tr>
<td>L04A</td>
<td>Fingolimod</td>
<td>2.0%</td>
<td>0.0%</td>
<td>1.5%</td>
<td>0.0%</td>
</tr>
<tr>
<td>M05B</td>
<td>Denosumab</td>
<td>1.9%</td>
<td>0.0%</td>
<td>0.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>28.8%</td>
<td>13.3%</td>
<td>25.7%</td>
<td>11.7%</td>
</tr>
</tbody>
</table>

Note: No inpatient data is available for Greece and Portugal.
Source: IMS Health and TLV analysis.

In Sweden, the TNF-alpha inhibitors etanercept and adalimumab account for a higher proportion of sales in outpatient care compared to other countries. This is likely because these are handled in outpatient care in Sweden, while they are more widely used in inpatient care in other countries.

5.1.2 Pharmaceutical management varies between countries

The management of new and/or expensive pharmaceuticals varies between different countries. In Sweden, pharmaceuticals suitable to be handled by the individual are distributed through prescription within outpatient care – regardless of how expensive the pharmaceutical is. This management varies in other countries. A number of countries have chosen to manage expensive pharmaceuticals as part of inpatient care associated with a hospital. Reasons for this include having better management and control over the pharmaceutical’s use. Another reason is that it may be easier and less costly to procedure pharmaceuticals through the hospitals.

This section describes the total sales value of the substances that are available in Sweden, on which the sample of pharmaceuticals in this report is based. It includes all preparations of these substances in other countries, regardless of whether they are available in Sweden. If there are other substances used in other countries, the value of such sales are not caught in other countries. Differences in sales value are affected by both prices and volume. Since the price differences between countries is relatively large, this description is not refined as to whether too much or too little of a pharmaceutical is used. figure 4 shows the cost per inhabitant in outpatient care per ATC1 code and country. In addition to pharmaceutical costs in outpatient care, there is information on pharmaceutical costs per inhabitant in inpatient care, both for the ATC codes L and J, and for all inpatient pharmaceuticals within the other ATC codes. The groups of pharmaceuticals for which Swedish use is highest will be weighted most heavily when calculating the price index.
The outpatient sales value of pharmaceuticals not exposed to competition is highest in Switzerland, followed by Ireland, Germany and Sweden (figure 4). Differences in the level of sales may be due to differences in price level and sales volumes, as well as the management of pharmaceuticals in outpatient and inpatient care. In several countries, sales of pharmaceuticals in outpatient care are very low within the ATC codes J and L. Within these ATC codes, there are relatively expensive pharmaceuticals to combat e.g. hepatitis C, cancer and rheumatic diseases. In several of the countries with low sales within these ATC codes, sales are relatively extensive in inpatient care. In particular, this applies to Denmark, Italy, the UK and Norway.

The structure of pharmaceutical sales in outpatient care thereby differs between Sweden and many countries. In figure 4, it is difficult to distinguish relative differences, although they can be seen in the ATC groups L and J. The difference in percentage of outpatient sales for different ATC groups is shown below in comparison with the equivalent percentages in Sweden.

In the countries where the bars are the lowest, the distribution of outpatient sales deviates the least from the Swedish (see figure 5). The ATC group that deviates most in percentage of total prescription sales is L. This group makes up almost one-third of sales (32 percent) in Sweden. In Italy, Denmark, Portugal, Greece and Spain, this proportion is 30 percent lower and, as shown in the figure above, these countries have only very small outpatient sales of the ATC group L.
As shown in the figure above, a low outpatient sales value within the ATC codes L and J does not mean that overall sales of these pharmaceuticals are low. In several countries with low outpatient sales, sales are high within inpatient care.

5.1.3 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 1,451 products in the sample for this segment. These pharmaceuticals are used as the 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.
Table 7. Degree of matching for pharmaceuticals not exposed to competition, quarter 1 2017 (more blue indicates a higher degree of matching, while more red indicates a lower degree of matching)

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>J</th>
<th>L</th>
<th>N</th>
<th>R</th>
<th>Other</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Germany</td>
<td>76%</td>
<td>60%</td>
<td>65%</td>
<td>88%</td>
<td>65%</td>
<td>64%</td>
<td>67%</td>
<td>69%</td>
</tr>
<tr>
<td>Austria</td>
<td>69%</td>
<td>55%</td>
<td>58%</td>
<td>76%</td>
<td>58%</td>
<td>50%</td>
<td>48%</td>
<td>58%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>73%</td>
<td>39%</td>
<td>60%</td>
<td>31%</td>
<td>63%</td>
<td>63%</td>
<td>61%</td>
<td>56%</td>
</tr>
<tr>
<td>Finland</td>
<td>65%</td>
<td>52%</td>
<td>27%</td>
<td>58%</td>
<td>59%</td>
<td>65%</td>
<td>54%</td>
<td>55%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>78%</td>
<td>54%</td>
<td>65%</td>
<td>35%</td>
<td>59%</td>
<td>67%</td>
<td>48%</td>
<td>54%</td>
</tr>
<tr>
<td>Switzerland</td>
<td>54%</td>
<td>38%</td>
<td>57%</td>
<td>69%</td>
<td>54%</td>
<td>53%</td>
<td>49%</td>
<td>54%</td>
</tr>
<tr>
<td>Ireland</td>
<td>63%</td>
<td>40%</td>
<td>30%</td>
<td>62%</td>
<td>50%</td>
<td>57%</td>
<td>52%</td>
<td>51%</td>
</tr>
<tr>
<td>Norway</td>
<td>69%</td>
<td>45%</td>
<td>35%</td>
<td>17%</td>
<td>55%</td>
<td>70%</td>
<td>61%</td>
<td>51%</td>
</tr>
<tr>
<td>Denmark</td>
<td>64%</td>
<td>21%</td>
<td>24%</td>
<td>32%</td>
<td>64%</td>
<td>69%</td>
<td>52%</td>
<td>49%</td>
</tr>
<tr>
<td>France</td>
<td>47%</td>
<td>36%</td>
<td>52%</td>
<td>68%</td>
<td>48%</td>
<td>52%</td>
<td>42%</td>
<td>48%</td>
</tr>
<tr>
<td>Belgium</td>
<td>56%</td>
<td>20%</td>
<td>47%</td>
<td>37%</td>
<td>43%</td>
<td>47%</td>
<td>43%</td>
<td>42%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>53%</td>
<td>31%</td>
<td>33%</td>
<td>55%</td>
<td>38%</td>
<td>52%</td>
<td>31%</td>
<td>39%</td>
</tr>
<tr>
<td>Spain</td>
<td>47%</td>
<td>16%</td>
<td>18%</td>
<td>22%</td>
<td>53%</td>
<td>54%</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>Italy</td>
<td>46%</td>
<td>31%</td>
<td>17%</td>
<td>19%</td>
<td>46%</td>
<td>52%</td>
<td>42%</td>
<td>38%</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>50%</td>
<td>26%</td>
<td>19%</td>
<td>37%</td>
<td>41%</td>
<td>49%</td>
<td>33%</td>
<td>36%</td>
</tr>
<tr>
<td>Hungary</td>
<td>41%</td>
<td>26%</td>
<td>30%</td>
<td>45%</td>
<td>31%</td>
<td>43%</td>
<td>35%</td>
<td>35%</td>
</tr>
<tr>
<td>Poland</td>
<td>34%</td>
<td>24%</td>
<td>16%</td>
<td>21%</td>
<td>40%</td>
<td>53%</td>
<td>37%</td>
<td>34%</td>
</tr>
<tr>
<td>Greece</td>
<td>53%</td>
<td>26%</td>
<td>16%</td>
<td>24%</td>
<td>36%</td>
<td>43%</td>
<td>35%</td>
<td>33%</td>
</tr>
<tr>
<td>Portugal</td>
<td>46%</td>
<td>14%</td>
<td>11%</td>
<td>10%</td>
<td>43%</td>
<td>46%</td>
<td>37%</td>
<td>32%</td>
</tr>
</tbody>
</table>

Unweighted average | 57% | 34% | 36% | 42% | 50% | 55% | 46% | 46% |

Source: IMS Health and TLV analysis.

On average, the degree of matching is highest in Germany (69 percent), followed by a group of five countries (Austria, the UK, Finland, the Netherlands and Switzerland) with a degree of matching between 54 and 58 percent. The lowest degree of matching is with Portugal, Greece, Poland and Hungary, which each have just over 30 percent. The degree of matching with our Nordic neighbours, Denmark and Norway, is about 50 percent.

The bilateral indexes 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 32 percent of Swedish pharmaceuticals. Bilateral indexes can thus only compare with Sweden, not any other country.

In terms of ATC groups, the degree of matching is highest within ATC A (alimentary tract and metabolism) and ATC R (respiratory system) since approximately 55 percent of the Swedish pharmaceuticals are found in these groups, on average. The lowest degree of matching is within ATC B (blood and blood-forming organs) and ATC J (anti-infectives for systemic use).

Differences in pharmaceutical use in outpatient care, the distribution between outpatient and inpatient care, and the number of pharmaceuticals are available in each
country and in Sweden are described above. There are differences between countries that may be relevant to consider when studying differences in the bilateral price index more closely. A high degree of matching and pharmaceutical use similar to Sweden, make the price comparison more robust. Comparisons with countries with a very low degree of matching are more difficult to generalise from since the comparison is only relevant to the small number of products the countries have in common. The prices that are compared are the list prices in outpatient care that applied during quarter 1 2017 in the respective country.

5.2 Index change compared to other countries

Compared to other countries, Sweden’s position has been relatively stable in recent years. The Swedish prices fall among the nine countries with the highest price of the 20 countries compared. There are eight countries with higher prices compared with Sweden. This was the case in 2017 as well as 2016 and 2015. In 2014, the prices in Sweden were slightly higher, with the price level in Sweden being arranged somewhat farther to the right in the figure. In late 2014 and early 2015, several popular pharmaceuticals in Sweden (e.g. Symbicort) were reassessed in connection with the 15-year rule. In the vast majority of countries, the 2015 index increased a relatively large amount compared to the 2014 index because of this reassessment.

Figure 6. Bilateral price index, pharmaceuticals not exposed to competition, Sweden = 100, quarter 1 2017.

Source: IMS Health and TLV analysis.

There are relatively small differences between 2016 and 2017, but the indexes in other countries have been generally slightly lower compared to Sweden during the period. The indexes in Norway and Ireland are most affected, and it is mainly price changes that contribute to this; see section 5.3.
The indexes are highest in Switzerland and Germany, as well as Ireland and Denmark, which has also been the case over time. The prices in Norway are now in line with Sweden, just below index 100. The price level in Finland is slightly lower than Sweden, with index 95. Of the largest countries in the comparison, France has the lowest index at 91. The index is lowest in Poland, followed by Greece.

5.2.1 Price index compared with other countries by ATC1 code

Table 8 shows how the differences in the bilateral price index are distributed between different ATC codes by country. With few exceptions, countries with a higher index compared to Sweden have a higher index in all ATC codes. ATC code L (antineoplastic and immunomodulating agents) account for a relatively large percentage of index differences in countries where the index is high compared to Sweden. The other ATC codes represent approximately the same amount of the remaining difference.

In countries with a low index and lower prices compared to Sweden, ATC codes L and N (nervous system) account for a large percentage of the difference, followed by R (respiratory system).

<table>
<thead>
<tr>
<th>Country</th>
<th>A</th>
<th>B</th>
<th>J</th>
<th>L</th>
<th>N</th>
<th>R</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland</td>
<td>-25</td>
<td>-2</td>
<td>-6</td>
<td>0</td>
<td>-3</td>
<td>-5</td>
<td>-3</td>
</tr>
<tr>
<td>Greece</td>
<td>-19</td>
<td>-2</td>
<td>-1</td>
<td>-1</td>
<td>-4</td>
<td>-4</td>
<td>-4</td>
</tr>
<tr>
<td>Slovakia</td>
<td>-15</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
<td>-6</td>
<td>-2</td>
<td>-2</td>
</tr>
<tr>
<td>Hungary</td>
<td>-12</td>
<td>-2</td>
<td>-2</td>
<td>-1</td>
<td>0</td>
<td>-2</td>
<td>-3</td>
</tr>
<tr>
<td>Portugal</td>
<td>-11</td>
<td>-1</td>
<td>0</td>
<td>0</td>
<td>-1</td>
<td>-6</td>
<td>0</td>
</tr>
<tr>
<td>France</td>
<td>-9</td>
<td>1</td>
<td>-1</td>
<td>-6</td>
<td>-2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>-8</td>
<td>-1</td>
<td>0</td>
<td>-1</td>
<td>-4</td>
<td>0</td>
<td>-1</td>
</tr>
<tr>
<td>Belgium</td>
<td>-8</td>
<td>-1</td>
<td>2</td>
<td>-1</td>
<td>-3</td>
<td>-2</td>
<td>-1</td>
</tr>
<tr>
<td>Spain</td>
<td>-7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-1</td>
<td>-4</td>
<td>0</td>
</tr>
<tr>
<td>Finland</td>
<td>-5</td>
<td>1</td>
<td>-1</td>
<td>0</td>
<td>-2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>Norway</td>
<td>-1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>-1</td>
<td>0</td>
<td>-1</td>
</tr>
<tr>
<td>Italy</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Austria</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>-1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Netherlands</td>
<td>8</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>-2</td>
<td>1</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>9</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Denmark</td>
<td>14</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Ireland</td>
<td>17</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Germany</td>
<td>21</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>11</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Switzerland</td>
<td>38</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>14</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.
5.2.2 Price index compared with other countries by age of pharmaceutical

An interesting aspect to highlight is the price dynamic over the life cycle of a pharmaceutical. However, the data set only provides access to price changes over a four-year period, which is a short period in this context. Thus, it is not possible to follow a pharmaceutical’s relative price trend over a longer period of time. Table 9 instead shows the bilateral price index per country and pharmaceutical grouped by age since approval. One cannot assume that the profile of new pharmaceuticals follows that of older ones. But it gives a good idea of differences in indexes between countries given how old the pharmaceuticals are. The pharmaceutical groups are those who are 16 years and older (covered by the 15-year rule in quarter 1 2017) followed by 5-year clusters. These clusters have about equal sales (approximately 20 percent of total sales), except for the oldest, which contains a larger number of pharmaceuticals.

Table 9. Bilateral price index per country and age of pharmaceutical, quarter 1 2017.

<table>
<thead>
<tr>
<th>Country</th>
<th>-5 years</th>
<th>6-10 years</th>
<th>11-15 years</th>
<th>16- years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland</td>
<td>80</td>
<td>76</td>
<td>71</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Greece</td>
<td>87</td>
<td>86</td>
<td>76</td>
<td>80</td>
<td>81</td>
</tr>
<tr>
<td>Slovakia</td>
<td>95</td>
<td>89</td>
<td>77</td>
<td>82</td>
<td>85</td>
</tr>
<tr>
<td>Hungary</td>
<td>106</td>
<td>90</td>
<td>78</td>
<td>85</td>
<td>88</td>
</tr>
<tr>
<td>Portugal</td>
<td>87</td>
<td>94</td>
<td>76</td>
<td>93</td>
<td>89</td>
</tr>
<tr>
<td>France</td>
<td>94</td>
<td>88</td>
<td>78</td>
<td>102</td>
<td>91</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>93</td>
<td>90</td>
<td>84</td>
<td>97</td>
<td>92</td>
</tr>
<tr>
<td>Belgium</td>
<td>95</td>
<td>100</td>
<td>87</td>
<td>90</td>
<td>92</td>
</tr>
<tr>
<td>Spain</td>
<td>96</td>
<td>98</td>
<td>89</td>
<td>92</td>
<td>93</td>
</tr>
<tr>
<td>Finland</td>
<td>98</td>
<td>91</td>
<td>86</td>
<td>101</td>
<td>95</td>
</tr>
<tr>
<td>Norway</td>
<td>102</td>
<td>95</td>
<td>88</td>
<td>104</td>
<td>99</td>
</tr>
<tr>
<td>Sweden</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Italy</td>
<td>102</td>
<td>104</td>
<td>93</td>
<td>103</td>
<td>102</td>
</tr>
<tr>
<td>Austria</td>
<td>106</td>
<td>99</td>
<td>97</td>
<td>118</td>
<td>107</td>
</tr>
<tr>
<td>Netherlands</td>
<td>105</td>
<td>103</td>
<td>97</td>
<td>118</td>
<td>108</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>100</td>
<td>100</td>
<td>98</td>
<td>125</td>
<td>109</td>
</tr>
<tr>
<td>Denmark</td>
<td>103</td>
<td>108</td>
<td>111</td>
<td>122</td>
<td>114</td>
</tr>
<tr>
<td>Ireland</td>
<td>119</td>
<td>115</td>
<td>110</td>
<td>123</td>
<td>117</td>
</tr>
<tr>
<td>Germany</td>
<td>106</td>
<td>112</td>
<td>118</td>
<td>141</td>
<td>121</td>
</tr>
<tr>
<td>Switzerland</td>
<td>120</td>
<td>131</td>
<td>123</td>
<td>163</td>
<td>138</td>
</tr>
</tbody>
</table>

| Position Sweden | 10      | 14       | 16        | 9        | 12 |
| Index cross-section | 102 | 99 | 96 | 105 | 101 |
| Percentage of sales | 20% | 22% | 20% | 38% | 100% |

Source: IMS Health and TLV analysis.

Generally speaking, prices for newly introduced pharmaceuticals (5 years and younger) are lower in Sweden. When sorted from the lowest to the highest index, Sweden ranks 10th, and the cross-sectional index for this age cluster is 102. For pharmaceuticals between 6 and 10 years of age, the Swedish prices are higher, and
Sweden is ranked 14th with a cross-sectional index of 99. For slightly older pharmaceuticals (11 to 15 years of age), Swedish prices are slightly higher. Sweden is ranked 16th and has a cross-sectional index of 96. But, for older pharmaceuticals (16 years and older), the Swedish prices are lower compared to other countries. Sweden ranks 9th for such pharmaceuticals and its index increases to 105.

5.2.3 Price index by different pricing models
Section 4.3 describes the pricing models in different countries. The different models can be divided into a few different categories:

- Countries that use informal, supporting reference pricing/IRP model as a supplement in pricing.
  - countries with the lowest price; this is made up of two countries – Spain and Italy
  - average of all prices in the reference countries; this is made up of five countries, including Germany, France and Finland.

- Countries that apply formal reference pricing/IRP model (10 countries)
  - countries with the lowest price; this is made up of four countries – Norway, Greece, Slovakia and Hungary.
  - average of all prices in the reference countries; this is made up of six countries, including the Netherlands and Austria.

- A group of three countries that use a pricing method other than some form of reference pricing: Sweden, Denmark and the UK.

Countries that apply pricing based on informal/supporting IRP by lowest price (Spain and Italy) have a cross-sectional index that on average is slightly lower than Sweden (index 99). Countries using informal/supporting IRP by average price also have an index just under 100, namely 98. However, this group includes Germany, which is the only country with an index over 100 in this group. If countries are excluded, the prices relative to Sweden drop to index 92 in the group ‘countries with informal/supporting IRP’.

\[\text{See Appendix 1 and 2 for a more detailed description of the pricing and reimbursement systems of the different countries.}\]

\[\text{Note that this is a cross-sectional index, where the same pharmaceuticals are used in the calculation. It is not possible to calculate an average based on the bilateral indexes per country.}\]
Countries with formal IRP by lowest price have the lowest index compared to Sweden (index 91). Countries that base pricing on formal IRP by average price on average have a higher index compared to Sweden (index 108). This group includes Switzerland, which has the highest index of all countries. However, even if Switzerland is excluded from the group the index is 103. In addition to Sweden (which is not included in the bar of the graph), the UK and Denmark are included in the group that uses another system.

5.3 Breakdown of change in total index over time

Table 10 shows the cross-sectional index between quarter 1 2014 and quarter 1 2017. The change between the years is divided into what effect the changed prices, volumes and product range (effect of introduced and discontinued products) has on the total index. Price index 2017 is in line with other countries with a cross-sectional index just over 100. Price index 2017 was slightly lower compared with 2016, but at the same level as 2015. Thus, prices in other countries have been slightly lower compared with Sweden between 2016 and 2017.

Between 2014 and 2017, the index in other countries increased relative to Sweden by 4.8 index points, from 96.0 to 100.8. This change is attributable to lower prices in Sweden. A number of major reassessments and the introduction of mandatory price reductions related to the 15-year rule caused the relative prices in Sweden to drop between 2014 and 2015, from 96 to 100.7. From 2015, the index has been just over 100 with only slight variations. Note that these indexes are not directly comparable with those presented in previous reports. This is because pharmaceuticals
change segment over time, from not exposed to competition to exposed to competition in the product-of-the-month segment. If a pharmaceutical with a high index the previous year is not included the next year, the index for the remaining pharmaceuticals will generally be higher and vice versa. See section 6 on pharmaceuticals that were added to the product-of-the-month segment between 2014 and 2017 and have thereby left the ‘not exposed to competition’ segment.


<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Price effect (constant volumes)*</td>
<td>97.0</td>
<td>101.6</td>
<td>102.8</td>
<td>102.0</td>
<td>-0.8</td>
<td>5.0</td>
</tr>
<tr>
<td>Volume effect (constant prices)*</td>
<td>102.2</td>
<td>102.0</td>
<td>101.9</td>
<td>102.0</td>
<td>0.1</td>
<td>-0.3</td>
</tr>
<tr>
<td>Effect, change in product range</td>
<td>-0.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*These calculations only include products that existed in all measurement periods.
Source: IMS Health and TLV analysis.*

Figure 8 shows within which ATC4 codes Swedish prices decreased most since 2014 compared to other countries. Note that an increased index means that the prices increased in other countries compared to Sweden. Between 2014 and 2017, prices increased most in other countries compared to Sweden in the areas obstructive airways diseases, R03A and R03B (e.g. Symbicort), immunosuppressant medicines, L04A (e.g. Etanercept), antiepileptic medicines, and lipid-lowering medicines (products that reduce cholesterol levels). It is within the areas where there were reassessments and mandatory price reductions related to the 15-year-rule\(^{25}\) that Swedish prices had a relatively large drop.

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\(^{25}\) The 15-year rule means that a pharmaceutical’s price is automatically reduced by 7.5 percent when it turns 15 years old, unless the original price was reduced prior to this.
5.3.1 Price effect per country, calculated as cross-sectional index

Viewed over the entire period 2014–2017, the prices in other countries increased by about 5 index points relative to Sweden. The major change occurred in 2014, while the changes in 2015 and 2016 cancel each other out. This is shown in the ‘average’ bar of the graph in figure 9. The only exception is Poland, where prices decreased somewhat compared to Sweden during the period after 2015. It is difficult to say anything about trends with so few years in the comparison, more than that there is a clear difference between 2014 and the subsequent years.

Source: IMS Health and TLV analysis.
Between 2016 and 2017, there are minor changes compared with other countries. In most of the countries, indexes and thereby prices decreased slightly in other countries compared to Sweden. The countries whose price changes deviate somewhat more are Norway and Ireland.

The prices in Norway continued to increase compared to Swedish prices, including between 2016 and 2017. The price index in Norway is now 99, which means that on average the prices are in line with Swedish prices. In total, the index in Norway increased by almost 20 index points compared with 2014. One explanation as to why prices in Norway are approaching those in Sweden can be the Norwegian Krone’s depreciation in value, compared to other countries. In the Norwegian model, the Norwegian prices are adjusted upwards if the Norwegian Krone drops in value. Such an adjustment is also applied when the exchange rate remains constant.

In contrast to the previous year, prices in Ireland decreased relatively severely between 2016 and 2017, falling by about 8 index points compared to Swedish prices. The prices are still higher in Ireland, with an index of 117. One explanation for Ireland’s lower price index in 2017 compared with 2016 is the new industry agreement, which puts a downward pressure on prices. Extensive price adjustments were implemented on 1 August 2016. Ireland’s reference countries were somewhat modified to include a larger number of low price countries, and Germany was eliminated. (See Appendix 2 for a description of the pricing and reimbursement systems in Ireland).
5.4 Price index by launch year

Table 11 shows a cross-sectional index over time by year of launch, which is based on when the substance received its first approval in the EU. The prices represent what applied in the respective year, while the volumes are kept constant at a running 12-month period up through March 2017. Index changes over time are attributable to both a change in prices and a change in the mix of pharmaceuticals. For recently launched pharmaceuticals in particular, the mix of pharmaceuticals changes for different years in the comparison.

Pharmaceuticals that are 15 years or older during the first quarter 2017 were subject to a mandatory price reduction under the 15-year rule. This applies to pharmaceuticals introduced up to and including 2001. The index for these age groupings of pharmaceuticals increased in other countries compared with Sweden over time. The greatest change was for pharmaceuticals launched in 2000, where the index increased from 86 in quarter 1 2014 to 99 in quarter 1 2017. The effect is greatest between the index for quarter 1 2014 and the index for quarter 1 2015, when the rule entered into force.

Table 11. Price index based on 2017 volumes, calculated as cross-section after year of launch quarter 1 2014–2017, and sales AIP rolling 12-month period through March 2017, MSEK.

<table>
<thead>
<tr>
<th>Year of launch</th>
<th>INDEX Q1 2017</th>
<th>INDEX Q1 2016</th>
<th>INDEX Q1 2015</th>
<th>INDEX Q1 2014</th>
<th>DIFFERENCE 2017-2014</th>
<th>SALES MSEK 2017 AIP</th>
<th>INDEX AVERAGE 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1999</td>
<td>109</td>
<td>110</td>
<td>107</td>
<td>103</td>
<td>6.1</td>
<td>2,680</td>
<td>105</td>
</tr>
<tr>
<td>2000</td>
<td>99</td>
<td>99</td>
<td>97</td>
<td>86</td>
<td>13.0</td>
<td>1,748</td>
<td></td>
</tr>
<tr>
<td>2001</td>
<td>110</td>
<td>108</td>
<td>114</td>
<td>107</td>
<td>3.2</td>
<td>177</td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>88</td>
<td>88</td>
<td>88</td>
<td>86</td>
<td>1.6</td>
<td>571</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>96</td>
<td>98</td>
<td>97</td>
<td>93</td>
<td>2.9</td>
<td>770</td>
<td>95</td>
</tr>
<tr>
<td>2004</td>
<td>98</td>
<td>102</td>
<td>104</td>
<td>100</td>
<td>-1.9</td>
<td>404</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>100</td>
<td>102</td>
<td>103</td>
<td>103</td>
<td>-2.3</td>
<td>229</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>95</td>
<td>96</td>
<td>95</td>
<td>95</td>
<td>0.1</td>
<td>443</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>98</td>
<td>101</td>
<td>102</td>
<td>94</td>
<td>3.6</td>
<td>657</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>100</td>
<td>100</td>
<td>101</td>
<td>101</td>
<td>-0.8</td>
<td>529</td>
<td>99</td>
</tr>
<tr>
<td>2009</td>
<td>96</td>
<td>95</td>
<td>95</td>
<td>96</td>
<td>-0.5</td>
<td>1,032</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>102</td>
<td>102</td>
<td>102</td>
<td>103</td>
<td>-1.2</td>
<td>241</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>101</td>
<td>103</td>
<td>105</td>
<td>107</td>
<td>-5.5</td>
<td>906</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>97</td>
<td>98</td>
<td>99</td>
<td>100</td>
<td>-3.4</td>
<td>273</td>
<td>102</td>
</tr>
<tr>
<td>2013</td>
<td>105</td>
<td>108</td>
<td>104</td>
<td>102</td>
<td>2.8</td>
<td>822</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>101</td>
<td>104</td>
<td>107</td>
<td>107</td>
<td>-4.8</td>
<td>459</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>97</td>
<td>111</td>
<td></td>
<td></td>
<td></td>
<td>245</td>
<td></td>
</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.

For other pharmaceuticals launched from 2002, the change varies over time. The index tends to decrease slightly over time for pharmaceuticals introduced relatively recently. Since the content of the indexes for different launch years vary over time in terms of pharmaceuticals and countries with sales, it is difficult to make individual
assessments regarding price effect. For several of the new pharmaceuticals, there are only a few data points in a small number of countries. Further data for a number of years is needed to be able to more deeply analyse the price trend over time for newer pharmaceuticals.

If pharmaceuticals are grouped by those subject to the 15-year rule during quarter 1 2017 (from and including launch year 2001) followed by launch years at 5-year intervals, the index for quarter 1 2017 is highest for newer pharmaceuticals (index 102) and for older pharmaceuticals (index 105). The price level is thus slightly higher in other countries for the youngest and oldest pharmaceuticals. The index and prices are marginally lower in other countries for pharmaceuticals launched between 2011 and 2007, with index 99, and slightly higher for pharmaceuticals launched between 2002 and 2006, with index 95. See section 5.2.2.

Pharmaceuticals launched in 2002 have the lowest index (88) quarter 1 2017. Methylphenidate (ATC3 code N03) for the treatment of ADHD contributes to the low index for this launch year. With an index of 96, launch year 2009 is a year of high sales and low prices in other countries. The TNF-alpha inhibitors Cimzia (L04AB05 certolizumab pegol) and Simponi (L04AB06 golimumab) were launched during this year and contribute to the low index. Victoza (A10BJ02 liraglutide), which is an anti-diabetic pharmaceutical used to lower blood sugar, also contributes to the low index of this year. For these launch years, the index has not changed considerably over time.

5.5 Price index across different ATC1 codes

Figure 12 shows the cross-sectional index per ATC1 code based on prices and on year and volumes for a running 12-month period through March 2017. The change over time is partly attributable to price changes and partly on the addition of new pharmaceuticals or countries in the cross-sectional index.

A comparison between different ATC1 codes shows that the Swedish prices for quarter 1 2017, calculated as cross-sectional index, are lower compared with other countries within the ATC1 codes A (alimentary tract), B (blood-forming organs), L (antineoplastic and immunomodulating agents), R (respiratory system) and other ATC codes. The Swedish prices are higher, i.e. the index for other countries is lower than 100, in the ATC groups J (anti-infectives) and N (nervous system).

Note that sales in Figure 10 are relatively low for ATC code J, approximately SEK 400 million compared with SEK 1,810 million in table 5. This is because several pharmaceuticals in this area are not managed by prescription in many countries and are therefore excluded from the comparison. The same pharmaceuticals in all countries are used when calculating the cross-sectional index. This means that extra

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26 For a pharmaceutical to be included in the cross-sectional index, there must be sales in at least 8 countries (40%)
caution must be taken when interpreting how the Swedish prices relate to other pharmaceuticals within this ATC code.

Figure 10. Cross-sectional index per ATC group, quarter 1, volumes for running 12-month period through March 2017, 2014–2017, plus sales value per ATC code.

Compared with 2014, it is within the ATC codes R, N and L that the price index in other countries increased relative to Sweden. Between 2016 and 2017, the index dropped within group J, B and R. The biggest changes in these groups during this period are described below.

Within ATC code B, it is anti-anaemic medicines (ATC B03) and antithrombotic agents (ATC B01) that reduce the index. In the case of antithrombotic agents, it is the price change for apixaban (Eliquis) in Poland in particular that reduces the index. Within J, it is antiviral medicines like Viekirax for the treatment of Hepatitis C and valganciclovir (Stelara) for the treatment of HIV that reduce the index. Within ATC code R, salmeterol, fluticasone (Seritide) and budesonide (Pulmicort) pulled down the 2017 index compared to 2016.

5.6 Price index where there are managed entry agreements is in line with other countries

This section analyses how Swedish prices relate to other countries regarding pharmaceuticals where there are managed entry agreements between Swedish county councils and companies.
A managed entry agreement is a contract between the county councils and a pharmaceutical company, and may be one of several grounds used by TLV when deciding on pricing and reimbursement status. New pharmaceuticals are being introduced earlier and earlier, and some pharmaceuticals are sometimes associated with uncertainties regarding use and efficacy in clinical practice. Because of this development, risk sharing through managed entry agreements regarding uncertainties about use and efficacy is an increasingly important tool for TLV and the county councils in their management of uncertainties. Managed entry agreements also have the potential to be a powerful tool for creating competition and pressing down costs within established pharmaceutical areas where no competition or downward pressure on prices has occurred for various reasons. Within the area TNF-alpha inhibitors, for example, competition has arisen via the introduction of biosimilars.

The analysis covers all pharmaceuticals that have had a managed entry agreement. See Appendix 2 for the pharmaceuticals subject to a managed entry agreement. These include some older pharmaceuticals, particularly biosimilars within the area TNF-alpha inhibitors, where there is competition but not within the framework of the automatic substitution procedure of the product-of-the-month system. The pharmaceuticals for which there has been a managed entry agreement through March 2017 account for almost one-quarter of the total sales within the segment ‘not exposed to competition’. In Sweden, these pharmaceuticals are almost exclusively managed in outpatient care (i.e. 100 percent), while the average for all countries is about 50 percent. This means that several countries manage these pharmaceuticals within inpatient care.

Table 12. Price index cross-section for pharmaceuticals divided into pharmaceuticals with and without managed entry agreement in Sweden

<table>
<thead>
<tr>
<th></th>
<th>Cross-sectional index 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>No managed entry agreement</td>
<td>100.7</td>
</tr>
<tr>
<td>Managed entry agreement exists</td>
<td>101.6</td>
</tr>
<tr>
<td>Index total</td>
<td>100.8</td>
</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.

On average, the cross-sectional index for all pharmaceuticals is 100.8 for quarter 1 2017. For pharmaceuticals subjected to a managed entry agreement, the index is slightly higher at 101.6. Thus, the price index for the pharmaceuticals subject by managed entry agreements is generally not higher compared with other pharmaceuticals relative to other countries, rather the opposite. Note that these indexes are calculated based on set prices and do not include rebates.

Figure 11 shows the bilateral price index per country for pharmaceuticals with a managed entry agreement. The degree of matching varies between the countries since several countries manage this type of pharmaceutical in inpatient care. Spain and Portugal have no sales of these pharmaceuticals in outpatient care. In this figure, the prices for all pharmaceuticals found in each country are compared with corresponding pharmaceuticals in Sweden.
On average, less than half of the pharmaceuticals (substance, dosage form and strength) subject to managed entry agreements in Sweden are found in other countries. The degree of matching varies between 6 percent in Poland and 9 percent in Italy up to 100 percent in Germany and 74 percent in Switzerland and Slovakia. Sweden’s price level for pharmaceuticals with managed entry agreements is in the lower half of all countries, with a rank of 8 out of 20 countries when sorted from lowest to highest index. Note that neither Spain nor Portugal has any pharmaceuticals in outpatient care that are subject to managed entry agreements. Sweden is the country with the 12th highest price index seen for all pharmaceuticals (see figure 6).

Figure 11. Index per country for pharmaceuticals with a managed entry agreement, bilateral index quarter 1 2017.

The index for Poland for these pharmaceuticals is lowest from the perspective of all pharmaceuticals, but they are in the middle of all the countries when it comes to pharmaceuticals with managed entry agreement. There is only one substance with a managed entry agreement that is found in Poland, and the list price for this substance is relatively high in Poland. The index for these pharmaceuticals should therefore be interpreted with some caution. Several countries in addition to Sweden may have different types of agreements that are linked to these pharmaceuticals but are not reflected in list prices.
6 Results: pharmaceuticals exposed to competition (within the product-of-the-month system)

The segment ‘pharmaceuticals exposed to competition’ includes all pharmaceutical groups in the sample found in the product-of-the-month system in March 2017. In total, segment sales in Sweden were around SEK 3.9 billion (AIP running 12-month period through March 2017). This represents 19 percent of the sales in the sample for this survey. Sweden is found among the three countries with the lowest prices in the sample.

Between 2014 and 2017, the Swedish prices decreased relative to all countries except Ireland and the Netherlands. During the study period, new products were continuously added to the ‘product-of-the-month system’ as competition arose when a pharmaceutical lost its patents. These products contributed to a fall in Swedish prices by 9 index points compared with other countries. However, a deeper analysis of the new pharmaceuticals that entered the ‘product-of-the-month system’ shows that the Swedish system is poorer than that of other countries in relation to pharmaceuticals where substitutability did not work well.

6.1 Description of pharmaceuticals exposed to competition within the product-of-the-month system

This section describes how the products available in Sweden are used in the other countries included in the survey. All analyses are based on products available in Sweden. If a product that is not available in Sweden is used in a certain area in another country, it is not included in the analysis.

The table below shows the top ten substances in this segment abroad (countries that are not Sweden). The substance account for 39 percent of the use in volume abroad. In Sweden, these substances account for 28 percent of use. The biggest difference in use is for pantoprazole (selective proton-pump inhibitor), which is more heavily used outside of Sweden.

The five treatment areas (ATC1 codes) that account for the largest sales volume in the product-of-the-month system are cardiovascular system (C), nervous system (N), alimentary tract and metabolism (A), respiratory system (R), genitourinary system and reproductive hormones (G) and musculoskeletal system (M). These areas together account for more than 90 percent of the use in almost all countries (in Greece they account for 88 percent).

27 See Terms and concepts for a listing of the 14 main groups of the ATC system.
Table 13. The ten substances within the product-of-the-month system with the highest sales volume abroad, running 12-month period through March 2017.

<table>
<thead>
<tr>
<th>ATC 4</th>
<th>Substance</th>
<th>Percentage of use (volume) abroad</th>
<th>Percentage of sales value abroad</th>
<th>Percentage of use (volume) Sweden</th>
<th>Percentage of sales value Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>A10B</td>
<td>Metformin</td>
<td>7.2%</td>
<td>1.6%</td>
<td>6.6%</td>
<td>1.2%</td>
</tr>
<tr>
<td>C07A</td>
<td>Bisoprolol</td>
<td>4.8%</td>
<td>1.9%</td>
<td>2.0%</td>
<td>0.9%</td>
</tr>
<tr>
<td>C10A</td>
<td>Atorvastatin</td>
<td>4.6%</td>
<td>5.5%</td>
<td>3.1%</td>
<td>2.0%</td>
</tr>
<tr>
<td>A02B</td>
<td>Omeprazole</td>
<td>4.4%</td>
<td>2.7%</td>
<td>3.6%</td>
<td>1.4%</td>
</tr>
<tr>
<td>A02B</td>
<td>Pantoprazole</td>
<td>4.3%</td>
<td>4.0%</td>
<td>0.3%</td>
<td>0.1%</td>
</tr>
<tr>
<td>C10A</td>
<td>Simvastatin</td>
<td>4.1%</td>
<td>1.9%</td>
<td>3.6%</td>
<td>0.7%</td>
</tr>
<tr>
<td>C08C</td>
<td>Amlodipine</td>
<td>3.7%</td>
<td>1.2%</td>
<td>3.7%</td>
<td>0.6%</td>
</tr>
<tr>
<td>C09A</td>
<td>Ramipril</td>
<td>3.5%</td>
<td>1.5%</td>
<td>1.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td>R01A</td>
<td>Mometasone furoate</td>
<td>2.7%</td>
<td>0.8%</td>
<td>3.8%</td>
<td>1.3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>39.4%</strong></td>
<td><strong>21.0%</strong></td>
<td><strong>28.2%</strong></td>
<td><strong>8.5%</strong></td>
</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.

The groups of pharmaceuticals for which Swedish use is greatest will be weighted most heavily when calculating the price index. The country whose per capita use differs the most from Sweden in this segment is Switzerland, whose use is less than half of the use in Sweden. The countries where the use is most similar to Sweden are the UK and Finland.

Figure 12. Per capita use grouped by ATC1 level and country for pharmaceuticals sold within the product-of-the-month system in Sweden, running 12-month period through March 2017.

Source: IMS Health and TLV analysis.

A big difference in use may be because the choice of which pharmaceutical is used for treatment varies greatly between countries or because a specific treatment is carried out within inpatient care in one of the countries. For those countries where the use differs greatly from the use in Sweden, it becomes more difficult to interpret the results of the price comparison.
For products in the product-of-the-month system, use is largely carried out in outpatient care. In all countries except the Czech Republic, over 95 percent of use is in outpatient care (for the Czech Republic it is 88 percent).

### 6.1.1 Degree of matching

The degree of matching shows the proportion of Swedish products that have sales in another country. Sweden has a total of 641 products in the sample for this segment. In the figure below, the degree of matching is broken down to the ATC1 level. The ATC group with the highest degree of matching among the countries is A, while the group with the lowest is R. The degree of matching is highest in Germany, where 75 percent of the Swedish products are available. Generally speaking, the degree of matching is high for all groups. The only ATC groups that are below 40 percent are R and G, and then only in a small number of countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>A</th>
<th>C</th>
<th>G</th>
<th>M</th>
<th>N</th>
<th>R</th>
<th>Other ATCs</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Germany</td>
<td>84%</td>
<td>86%</td>
<td>65%</td>
<td>91%</td>
<td>71%</td>
<td>71%</td>
<td>71%</td>
<td>75%</td>
</tr>
<tr>
<td>Denmark</td>
<td>80%</td>
<td>78%</td>
<td>65%</td>
<td>91%</td>
<td>71%</td>
<td>52%</td>
<td>66%</td>
<td>72%</td>
</tr>
<tr>
<td>Finland</td>
<td>87%</td>
<td>76%</td>
<td>57%</td>
<td>77%</td>
<td>70%</td>
<td>65%</td>
<td>67%</td>
<td>71%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>78%</td>
<td>74%</td>
<td>74%</td>
<td>91%</td>
<td>62%</td>
<td>68%</td>
<td>60%</td>
<td>67%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>87%</td>
<td>66%</td>
<td>65%</td>
<td>82%</td>
<td>63%</td>
<td>58%</td>
<td>61%</td>
<td>65%</td>
</tr>
<tr>
<td>Austria</td>
<td>78%</td>
<td>75%</td>
<td>52%</td>
<td>73%</td>
<td>63%</td>
<td>39%</td>
<td>63%</td>
<td>65%</td>
</tr>
<tr>
<td>Ireland</td>
<td>89%</td>
<td>76%</td>
<td>57%</td>
<td>68%</td>
<td>58%</td>
<td>58%</td>
<td>62%</td>
<td>65%</td>
</tr>
<tr>
<td>Switzerland</td>
<td>84%</td>
<td>68%</td>
<td>61%</td>
<td>82%</td>
<td>58%</td>
<td>55%</td>
<td>69%</td>
<td>65%</td>
</tr>
<tr>
<td>Norway</td>
<td>87%</td>
<td>73%</td>
<td>43%</td>
<td>68%</td>
<td>64%</td>
<td>71%</td>
<td>42%</td>
<td>63%</td>
</tr>
<tr>
<td>Spain</td>
<td>69%</td>
<td>68%</td>
<td>65%</td>
<td>50%</td>
<td>60%</td>
<td>68%</td>
<td>52%</td>
<td>61%</td>
</tr>
<tr>
<td>Italy</td>
<td>76%</td>
<td>64%</td>
<td>52%</td>
<td>59%</td>
<td>49%</td>
<td>55%</td>
<td>60%</td>
<td>56%</td>
</tr>
<tr>
<td>Belgium</td>
<td>67%</td>
<td>62%</td>
<td>48%</td>
<td>82%</td>
<td>51%</td>
<td>61%</td>
<td>52%</td>
<td>56%</td>
</tr>
<tr>
<td>Portugal</td>
<td>69%</td>
<td>62%</td>
<td>26%</td>
<td>73%</td>
<td>56%</td>
<td>55%</td>
<td>44%</td>
<td>55%</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>58%</td>
<td>71%</td>
<td>52%</td>
<td>50%</td>
<td>52%</td>
<td>39%</td>
<td>50%</td>
<td>55%</td>
</tr>
<tr>
<td>France</td>
<td>71%</td>
<td>63%</td>
<td>43%</td>
<td>64%</td>
<td>50%</td>
<td>65%</td>
<td>49%</td>
<td>55%</td>
</tr>
<tr>
<td>Poland</td>
<td>62%</td>
<td>65%</td>
<td>70%</td>
<td>77%</td>
<td>47%</td>
<td>52%</td>
<td>53%</td>
<td>54%</td>
</tr>
<tr>
<td>Hungary</td>
<td>64%</td>
<td>65%</td>
<td>35%</td>
<td>64%</td>
<td>49%</td>
<td>26%</td>
<td>57%</td>
<td>53%</td>
</tr>
<tr>
<td>Greece</td>
<td>71%</td>
<td>58%</td>
<td>35%</td>
<td>59%</td>
<td>49%</td>
<td>58%</td>
<td>49%</td>
<td>53%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>58%</td>
<td>62%</td>
<td>48%</td>
<td>55%</td>
<td>49%</td>
<td>42%</td>
<td>51%</td>
<td>52%</td>
</tr>
</tbody>
</table>

**Average** | 77% | 71% | 56% | 74% | 60% | 59% | 59% | 63% |

*Source: IMS Health and TLV analysis.*

A high degree of matching and pharmaceutical use similar to that in Sweden make the price comparison more robust.

### 6.2 Sweden has low prices for pharmaceuticals in the product-of-the-month system

Within the segment ‘pharmaceuticals in the product-of-the-month system’, the Swedish prices are among the three lowest. The Netherlands, Sweden and Denmark
create a group of countries where prices differ from the other countries. These countries steer sales to a large extent to the cheapest product where there is a possibility of substitution. The differences between the countries are significantly greater than for pharmaceuticals not exposed to competition. In Switzerland, where prices are the most expensive, the price for these products is 356 percent higher than in Sweden.

Between quarter 1 2014 and quarter 1 2015, the level of other countries decreased relative to Sweden. Between quarter 1 2015 and quarter 1 2016, Sweden’s index grew stronger relative to other countries. This trend continued between quarter 1 2016 and quarter 1 2017. Between 2014 and 2017, the Swedish index decreased relative to all countries except Ireland and the Netherlands.

To see which groups of pharmaceuticals that explain the difference in index between the countries, the effect of the different ATC1 levels on the bilateral index has been analysed. The analysis describes how the different groups contribute to a difference compared to Sweden, which has index 100. For example, Austria’s index is 149 points higher than Sweden and this is mainly because the areas C (cardiovascular system) and N (nervous system) have an upwards effect on the Austrian index by 48 and 41 index points, respectively.
### Table 15. Effect of different ATC1 groups on the bilateral price index in the product-of-the-month system, quarter 1 2017.

<table>
<thead>
<tr>
<th>Country</th>
<th>Total difference compared to Sweden</th>
<th>A</th>
<th>C</th>
<th>G</th>
<th>M</th>
<th>N</th>
<th>R</th>
<th>Other ATCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>125</td>
<td>13</td>
<td>43</td>
<td>8</td>
<td>3</td>
<td>36</td>
<td>3</td>
<td>19</td>
</tr>
<tr>
<td>Denmark</td>
<td>9</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>-6</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Finland</td>
<td>92</td>
<td>9</td>
<td>51</td>
<td>7</td>
<td>3</td>
<td>10</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>France</td>
<td>101</td>
<td>17</td>
<td>34</td>
<td>9</td>
<td>5</td>
<td>16</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Greece</td>
<td>146</td>
<td>19</td>
<td>78</td>
<td>5</td>
<td>4</td>
<td>23</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Ireland</td>
<td>131</td>
<td>10</td>
<td>49</td>
<td>7</td>
<td>2</td>
<td>38</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>Italy</td>
<td>167</td>
<td>20</td>
<td>54</td>
<td>12</td>
<td>4</td>
<td>47</td>
<td>12</td>
<td>19</td>
</tr>
<tr>
<td>Netherlands</td>
<td>9</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Norway</td>
<td>176</td>
<td>26</td>
<td>75</td>
<td>5</td>
<td>4</td>
<td>45</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>Poland</td>
<td>47</td>
<td>5</td>
<td>24</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Portugal</td>
<td>65</td>
<td>7</td>
<td>31</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Switzerland</td>
<td>356</td>
<td>41</td>
<td>119</td>
<td>17</td>
<td>8</td>
<td>111</td>
<td>10</td>
<td>49</td>
</tr>
<tr>
<td>Slovakia</td>
<td>39</td>
<td>3</td>
<td>22</td>
<td>7</td>
<td>1</td>
<td>-4</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Spain</td>
<td>93</td>
<td>7</td>
<td>34</td>
<td>8</td>
<td>2</td>
<td>23</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>84</td>
<td>3</td>
<td>35</td>
<td>3</td>
<td>1</td>
<td>28</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>155</td>
<td>8</td>
<td>59</td>
<td>7</td>
<td>2</td>
<td>40</td>
<td>6</td>
<td>32</td>
</tr>
<tr>
<td>Germany</td>
<td>110</td>
<td>10</td>
<td>19</td>
<td>6</td>
<td>3</td>
<td>39</td>
<td>6</td>
<td>28</td>
</tr>
<tr>
<td>Hungary</td>
<td>84</td>
<td>14</td>
<td>27</td>
<td>5</td>
<td>2</td>
<td>19</td>
<td>2</td>
<td>14</td>
</tr>
<tr>
<td>Austria</td>
<td>149</td>
<td>21</td>
<td>48</td>
<td>5</td>
<td>5</td>
<td>41</td>
<td>5</td>
<td>24</td>
</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.

The ATC1 groups that account the most for why pharmaceuticals exposed to competition in Sweden are cheaper than the other countries are C and N. For C, the index is higher in all other countries, and for N it is only Denmark, the Netherlands and Slovakia that are cheaper. However, there may be substances in the groups that are more expensive in Sweden.

### 6.3 Changes between the periods

Between quarter 1 2014 and quarter 1 2015, the price differences between Sweden and other countries decreased for products exposed to competition. However, the differences increased again between 2015 and 2016. The trend continued between 2016 and 2017, and between 2014 and 2017 the Swedish index improved by 25 index points compared with the average of the other countries.

The table below describes how a change in price, volume and range between the periods affects the index change. ‘With constant volumes’ shows the effect of a price change, ‘With constant prices’ shows the effect of a volume change, and ‘Effect, change in product range’ shows the effect of introduced and discontinued products.
The effect with the greatest impact on the index change between the periods is the price effect (With constant volumes). The rest of the analyses in this section examine the price effect. This means that volumes are kept constant at the 2017 level, and only products that existed during all four periods are included.

Figure 14 shows the price effect for the respective country plus for the average of all countries. The figure shows that the prices in all countries reduced relative to Sweden between 2014 and 2015. Between 2015 and 2016, the prices of other countries increased compared with the Swedish prices. The increase continued between 2016 and 2017 in all countries except Ireland and Denmark. In total between 2014 and 2017, Swedish prices decreased compared with all countries except Ireland and the Netherlands, and on average the prices of other countries increased by 24 index points.

One explanation as to why the Irish price level have move toward the Swedish one is that Ireland started at a relatively high index (267) quarter 1 2014. Ireland also introduced new rules for how generic products are priced.
If the analysis instead focuses on the price effect broken down by ATC1 level, Figure 15 shows that groups C (cardiovascular system) and N (nervous system) plus the ATC groups classified as ‘other’ contributed to a reduction of Swedish prices relative to other countries.

**Figure 15. Price calculated as cross-sectional index between Q1 2014 and Q1 2017.**

![Bar chart showing price effect by ATC groups](chart.png)

*Source: IMS Health and TLV analysis.*

Within C (cardiovascular system) and N (nervous system), there are many substances that contributed to the development. Under ‘other ATCs’, the development was primarily affected by the substance imatinib. The price development for imatinib is described in more detail in the next section.

6.3.1 Products added to the product-of-the-month system between March 2014 and March 2017

Several substances lost their patent and have thereby become exposed to competition between March 2014 and March 2017. Over a rolling 12-month period through March 2017, these substances amounted to 1.1 billion of the total 3.9 billion products classified as part of the product-of-the-month system. During all periods, substances that became exposed to competition within the measurement period contributed to a reduction of Swedish prices relative to other countries. Of the total price effect of 24 index points, these products account for 9 index points.
For most substances added to the product-of-the-month system, Swedish prices dropped relative to other countries, and the cost difference compared to the average of the countries for these products is about SEK 200 million. The total cost difference compared to the average of the countries is about 3 billion. The biggest cost difference is the one with imatinib, where the original Glivec became exposed to competition in December 2016.

Table 17. Cost difference index, price effect and number of countries that are more expensive than Sweden Q1 2017 for the 10 substances added to the product-of-the-month system between March 2014 and March 2017 with the biggest cost difference compared to Sweden.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cost difference 2017 (MSEK)</th>
<th>Average index Q1 2017</th>
<th>Max. index Q1 2017</th>
<th>Min. index Q1 2017</th>
<th>Price effect between 2014 and 2017</th>
<th>Number of countries more expensive than Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imatinib</td>
<td>101</td>
<td>273</td>
<td>449</td>
<td>74</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Pregabalin</td>
<td>-54</td>
<td>70</td>
<td>153</td>
<td>37</td>
<td>-2</td>
<td>2</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>45</td>
<td>284</td>
<td>646</td>
<td>76</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>35</td>
<td>225</td>
<td>645</td>
<td>13</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td>Drospirenone, etinylestradiol</td>
<td>26</td>
<td>409</td>
<td>972</td>
<td>235</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>-25</td>
<td>73</td>
<td>104</td>
<td>35</td>
<td>-1</td>
<td>19</td>
</tr>
<tr>
<td>Eplerenone</td>
<td>21</td>
<td>427</td>
<td>1,017</td>
<td>99</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Escitalopram</td>
<td>19</td>
<td>153</td>
<td>429</td>
<td>48</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Desogestrel</td>
<td>19</td>
<td>654</td>
<td>1,782</td>
<td>100</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>Rasagiline</td>
<td>16</td>
<td>883</td>
<td>2,072</td>
<td>143</td>
<td>1</td>
<td>19</td>
</tr>
</tbody>
</table>

Source: IMS Health and TLV analysis.
Two substances (pregabalin and methylphenidate) stand out as they have a negative cost difference. If the Swedish prices had been in line with the average of other countries, the costs would have decreased by SEK 54 million and 25 million, respectively. In addition, only two of the other 19 countries have higher prices than Sweden. One explanation to this is that the substitutability for these substances is limited in Sweden. This means that price competition does not arise, and because the Swedish system relies heavily on price competition it does not work as well as the systems in other countries.
7 Sensitivity analysis

7.1 Exchange rate effects

One factor that affects relative prices over time is change in exchange rates. If the currency of a country grows stronger, prices in other countries will seem to have dropped relative to this country, even if they are nominally unchanged in the respective country’s currency.

This report is based on the average exchange rate for quarter 1 2017 (which is described in section 3.5). To exemplify the effect that changes in exchange rates may have between the different periods, the figure below shows the bilateral index for products exposed to competition for Q1 2017 broken down according to the average exchange rates for Q1 2014, 2015, 2016 and 2017. Norway and the UK show the largest change.

*Figure 17. Bilateral price index broken down by exchange rate for pharmaceuticals not exposed to competition quarter 1 2017.*

7.2 Effects of changing base country for volume weighting

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 2012.²⁸

The reason why the country whose sales volumes are used as the base weight tend 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 change of base country for Sweden, France, the Netherlands and the UK is compared in the analysis. These countries were chosen because they are part of different pricing categories for pharmaceuticals not exposed to competition (see, for example, Table 4) – 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. This type of analysis, but with a change of base country to Finnish and Austrian weights, was also done in TLV’s international price comparison for 2015 and 2016.

Earlier in the report, the pharmaceuticals were divided into segments based on the conditions for competition in Sweden.

1. Pharmaceuticals not exposed to competition and
2. Pharmaceuticals exposed to competition (within the product-of-the-month system)

The segment ‘pharmaceuticals in the product-of-the-month system’ includes all pharmaceuticals available as substitutable pharmaceuticals for the product-of-the-month as per March 2017. The volume weight analysis instead applied IMS’s definition of competition. The segment ‘pharmaceuticals exposed to competition’ can include both pharmaceuticals not exposed to competition and pharmaceuticals in the product-of-the-month system (as described in section 2.1). The difference depends on how the substitutability of pharmaceuticals is defined.

IMS’s definition of the prerequisite for competition is broader in several respects than that determined by the Swedish Medical Products Agency, which means that the product-of-the-month system includes fewer products than IMS’s definition of pharmaceuticals exposed to competition. For this reason, IMS’s broader definition of the ‘exposed to competition’ segment is used in the sensitivity analysis with change of base country. Compared to the Swedish volume used in the rest of the analysis, the narrower Swedish perspective – pharmaceutical in the product-of-the-month system or not – has a volume that is too small if one changes to the sales volume of other countries. The index and index differences in the base effect analysis should be considered individually and are not comparable with other indexes in the report because several substances change category.

7.2.1 Change of base country for pharmaceuticals not exposed to competition
The following table shows the order in which the price indexes of the countries falls into upon change of base weighting from Swedish to other countries’ sales volumes.
Table 18. Ranking 1–20, lowest to highest, bilateral price index with Swedish, French, Dutch and UK sales volumes as volume weights Quarter 1 2017 for pharmaceuticals not exposed to competition.

<table>
<thead>
<tr>
<th>Country</th>
<th>Swedish weight</th>
<th>French weight</th>
<th>Dutch weight</th>
<th>UK weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Greece</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Slovakia</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>France</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>5</td>
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<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Hungary</td>
<td>6</td>
<td>7</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Portugal</td>
<td>7</td>
<td>6</td>
<td>7</td>
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<tr>
<td>Finland</td>
<td>8</td>
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<tr>
<td>Belgium</td>
<td>9</td>
<td>12</td>
<td>10</td>
<td>13</td>
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<tr>
<td>Norway</td>
<td>10</td>
<td>9</td>
<td>9</td>
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</tr>
<tr>
<td>United Kingdom</td>
<td>11</td>
<td>11</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Spain</td>
<td>12</td>
<td>10</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td><strong>Sweden</strong></td>
<td><strong>13</strong></td>
<td><strong>13</strong></td>
<td><strong>13</strong></td>
<td><strong>12</strong></td>
</tr>
<tr>
<td>Italy</td>
<td>14</td>
<td>14</td>
<td>14</td>
<td>14</td>
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<tr>
<td>Austria</td>
<td>15</td>
<td>15</td>
<td>16</td>
<td>16</td>
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<tr>
<td>Netherlands</td>
<td>16</td>
<td>16</td>
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<td>15</td>
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<tr>
<td>Denmark</td>
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<td>18</td>
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<tr>
<td>Ireland</td>
<td>18</td>
<td>18</td>
<td>17</td>
<td>19</td>
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<tr>
<td>Germany</td>
<td>19</td>
<td>19</td>
<td>19</td>
<td>17</td>
</tr>
<tr>
<td>Switzerland</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

Note: IMS’s broader definition of the segments ‘exposed to competition’ and ‘not exposed to competition’ is used in the sensitivity analysis with change of base country.
Source: IMS and TLV analysis.

Five of the 20 countries retain their position, ranked 1-20, regardless of which country’s sales volumes is used as base weight. These are Slovakia, Czech Republic, Finland, Italy and Switzerland. Sweden’s position is stable, with a ranking of 12th or 13th among the 20 countries. There are also relatively small movements for other countries. France’s position is 4th or 6th. The Netherlands’ position is 15th or 16th. The UK’s position is 10th or 11th.

The following figure illustrates deviations from the Swedish index in percentage points (index points).
Figure 18. Bilateral price index with Swedish, French and Austrian sales volumes as volume weights and relative deviations from the Swedish index quarter 1 2017 for pharmaceuticals not exposed to competition.

Note: The index of other countries’ base weight has been normalised so that Sweden is always 0, irrespective of whether it is Sweden’s or another country’s volume.
Note: IMS’s broader definition of the segments ‘exposed to competition’ and ‘not exposed to competition’ is used in the sensitivity analysis with change of base country.
Source: IMS and TLV analysis.

The difference in index between Sweden and the Netherlands is 10.9 with Swedish volume weights. With all else equal, the difference decreases to 6.1 if Austrian volume weights are used. In other words, the Dutch index for the ‘not exposed to competition’ segment becomes 4.9 percentage points lower relative to Sweden when the base volume is changed.

The results are similar for France. The difference in index between Sweden and France is -10.2 with Swedish volume weights. With all else equal, the difference increases to -13.1 if French volume weights are used. In other words, the French index for the ‘not exposed to competition’ segment becomes 2.9 percentage points lower relative to Sweden when the base volume is changed.

For the UK, there are small differences in the total for the segment. But, the difference nonetheless reduces somewhat if there is a switch to a British index.

Table 19. Relative impact on the index after change of base weight, price index bilaterally with Swedish and other countries’ sales volumes as volume weights quarter 1 2017 for pharmaceuticals not exposed to competition.

<table>
<thead>
<tr>
<th></th>
<th>Swedish weight</th>
<th>Sweden with French weight</th>
<th>Sweden with Dutch weight</th>
<th>Sweden with British weight</th>
<th>Difference Swedish weight</th>
<th>Difference other weight</th>
<th>Cumulative change (percentage points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>0.90</td>
<td>1.15</td>
<td>-10.2%</td>
<td>-13.1%</td>
<td>-2.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>1.11</td>
<td>0.94</td>
<td>10.9%</td>
<td>6.1%</td>
<td>-4.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>0.99</td>
<td>1.01</td>
<td>-1.2%</td>
<td>-0.9%</td>
<td>0.3%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: IMS’s broader definition of the segments ‘exposed to competition’ and ‘not exposed to competition’ is used in the sensitivity analysis with change of base country.
Source: IMS and TLV analysis.
7.2.2 Change of base country for pharmaceuticals exposed to competition

For the market segment ‘pharmaceuticals exposed to competition’ (according to the IMS definition, which is broader than the product-of-the-month definition analysed earlier), the ranking among the 20 countries changes slightly more than for the previous segment.

The following figure illustrates deviations from the Swedish index in percentage points (index points).

Table 20. Ranking 1–20, lowest to highest, bilateral price index with Swedish and other countries’ sales volumes as volume weights quarter 1 2017 for pharmaceuticals exposed to competition.

<table>
<thead>
<tr>
<th>Country</th>
<th>Swedish weight</th>
<th>French weight</th>
<th>Dutch weight</th>
<th>UK weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
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<td>Spain</td>
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<td>Finland</td>
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<td>Italy</td>
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<td>Ireland</td>
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<td>Austria</td>
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<td>Norway</td>
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</tr>
<tr>
<td>Switzerland</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

Note: The index of other countries’ base weight has been normalised so that Sweden is always 0, irrespective of whether it is Sweden’s or other country’s volume.
Note: IMS’s broader definition of the segments ‘exposed to competition’ and ‘not exposed to competition’ is used in the sensitivity analysis with change of base country.
Source: IMS and TLV analysis.

Only four countries retain the same position in the ranking regardless of which country’s base weight is used. These are Portugal, Austria, Norway and Switzerland.

Sweden’s position is lowest with Swedish weight, second lowest with British weight, and fourth lowest with French and Dutch weights. France’s position is 9th, 10th and 12th; the Netherlands’ position is 1st, 3rd and 5th; and the UK’s position is 7th, 11th, 13th and 14th depending on which country’s volume weight is used.

The following figure illustrates deviations from the Swedish index in percentage points (index points).
Figure 19. Bilateral price index with Swedish and other countries’ sales volumes as volume weights and relative deviations from the Swedish index quarter 1 2017 for pharmaceuticals exposed to competition.

The difference in index between Sweden and the Netherlands is 7.2 with Swedish volume weights. With all else equal, the difference decreases to -11.9 if Dutch volume weights are used. In other words, the Dutch index for the ‘exposed to competition’ segment becomes -19.1 percentage points lower relative to Sweden when the base volume is changed.

The difference in index between Sweden and France is 43.2 with Swedish volume weights. With all else equal, the difference decreases to 17.7 if French volume weights are used. In other words, the French index for the ‘not exposed to competition’ segment becomes -19.1 percentage points lower relative to Sweden when the base volume is changed. The difference with British weights exhibits values similar to the French ones, but with somewhat higher magnitudes.

Table 21. Relative impact on the index after change of base weight, price index bilaterally with Swedish and other countries’ sales volumes as volume weights quarter 1 2017 for pharmaceuticals exposed to competition.

<table>
<thead>
<tr>
<th>Country</th>
<th>Swedish weight</th>
<th>Sweden with French weight</th>
<th>Sweden with Dutch weight</th>
<th>Swedish with British weight</th>
<th>Difference Swedish weight</th>
<th>Difference other weight</th>
<th>Cumulative change (percentage points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>1.43</td>
<td>0.85</td>
<td>1.13</td>
<td>43.2%</td>
<td>17.7%</td>
<td>-25.5%</td>
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<tr>
<td>Netherlands</td>
<td>1.07</td>
<td>0.86</td>
<td>1.13</td>
<td>7.2%</td>
<td>-11.9%</td>
<td>-19.1%</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1.49</td>
<td>0.86</td>
<td>49.2%</td>
<td>15.6%</td>
<td>-33.6%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: IMS’s broader definition of the segments ‘exposed to competition’ and ‘not exposed to competition’ is used in the sensitivity analysis with change of base country. Source: IMS and TLV analysis.
The results of the sensitivity analysis with change of base country for volume weighting are consistent with the theory that the country whose sales volume is used tends to have a better outcome compared to when another country’s volume is used. This is mainly due to the fact that cheaper pharmaceuticals tend to have a higher level of use. However, the positions of the countries in terms of rank are generally stable.
8 Discussion

The Swedish prices within the segment ‘pharmaceuticals not exposed to competition’ (not in the product-of-the-month system) are in line with the prices in other countries, with an index of 101. The Swedish prices fall among the nine countries with the highest price of the 20 countries compared. There are eight countries with higher prices compared with Sweden. This was the case in 2017 as well as 2016 and 2015.

If you compare Swedish price level with other countries and group these by type of price model for the segment ‘pharmaceuticals not exposed to competition’, you find that countries that apply reference pricing as an informal/supporting part of pricing have prices just below the Swedish ones. The countries that apply formal reference pricing, i.e. use it as a main criterion, and that base the price assessment on the lowest price in comparison countries, prices are clearly lower than the Swedish ones, with an index of 91. Both countries that apply formal reference pricing and use average prices and countries that use a system other than reference pricing have higher prices than Sweden.

The indexes also vary depending on the age of the pharmaceutical. Prices of pharmaceuticals that are up to 5 years (launched up to 2012) and pharmaceuticals that are 16 years and older (launched in 2001 or before) are slightly lower in Sweden compared with other countries. For pharmaceuticals launched between 2011 and 2002, the prices are, on average, higher in Sweden than in other countries. It is not possible to assess the extent to which these differences depend on the dynamics of the pricing systems or whether it is just the nature of the pharmaceuticals launched these years that yields these results. Data is needed to further analyse the price dynamics over time and to distinguish random changes from trends.

When you analyse differences in price over ATC code, it is within the nervous system (ATC N) where Swedish prices are higher compared to other countries. This applies in particular to the antithrombotic agents. Within anti-infectives (ATC J), prices in Sweden are also somewhat higher in comparison with other countries. However, pharmaceuticals within this ATC code are managed to a greater extent within inpatient care at hospitals in other countries. This means that there is a small proportion of pharmaceuticals found in Sweden that are included in the analysis for this ATC code. This also applies to pharmaceuticals within ATC L (antineoplastic and immunomodulating agents). The index for ATC L is just over 100, which is the index for Sweden. But, there are several countries that manage pharmaceuticals within this ATC code within inpatient care.

Only official list prices are included in the comparison since it is only these prices that may be collected in a simple in a standardised way. Prices for procured pharmaceuticals that are not managed by prescription in outpatient care are thus not
captured in the comparison. Some countries have discounts of various kinds that are not reflected in the list price of a pharmaceutical. Sweden also has managed entry agreements that reduce the cost for a number of different pharmaceuticals including? pharmaceuticals for which efficacy is uncertain. Thus, it may be difficult to make direct comparisons for certain countries and pharmaceuticals. An increased degree of transparency, in cases where there is some form of rebate agreement or other type of agreement that results in a significant price deviation from an official list price, would facilitate interpretation of price comparisons.

As previously mentioned, it is the official list prices that are used in this report, and prices are weighted based on use. The starting point is mainly Swedish volumes since these are what is relevant from a Swedish perspective. It is thus price differences for pharmaceuticals that also have a large sales volume that have the greatest effect on the price comparison. It is important to take volumes into account when making price comparisons, to prevent large price differences for pharmaceuticals with low sales to have a disproportionate effect on the comparison.

It is also important to bear in mind that it is only the pharmaceuticals that are available bilaterally in Sweden and the respective comparison country that are included in the analysis. If any pharmaceutical in another country is managed completely via hospitals, it is not included in the price comparison. Comparisons can only be carried out on the mix of pharmaceuticals that match bilaterally. The existence of different forms of discounts and rebate agreements and their scope cannot be captured in a price comparison. There is no transparent compilation of such agreements or their scope. In Sweden as well, there are different types of agreements on risk sharing or refunds between the county councils and the companies.

If you compare the price index for the pharmaceuticals subject to managed entry agreements in Sweden with other countries, the prices are somewhat higher in other countries compared with Sweden. The index for pharmaceuticals with managed entry agreements is also somewhat higher compared with other pharmaceuticals. The Swedish prices for these pharmaceuticals are thus somewhat lower relative to other countries. There is great variation between countries when it comes to how many of the products with managed entry agreements in Sweden that are also available in the respective country. Spain and Portugal have no sales whatsoever for these pharmaceuticals in outpatient care, and less than 10 percent of these pharmaceuticals are available in Poland and Greece. In contrast, all of the pharmaceuticals available in Sweden are available in Germany, and more than 75 percent of them are available in Austria and Switzerland.

How the index relative to other countries develops over time is probably quite a good yardstick of how dynamic and adaptable the Swedish system is. Within the segment ‘not exposed to competition’, the development has been relatively stable over time. In 2014, the cross-sectional index was 96 and the Swedish prices were slightly over those of other countries. Swedish was ranked 16th among the other 20 countries. Between 2014 and 2015, the relative prices in Sweden decreased rather
greatly as a result of more extensive reassessments of pharmaceuticals in the benefits scheme and as the result of introducing mandatory price 7.5 percent price reductions for older pharmaceuticals (15-year rule). In 2015, the index increased to about 101, which means that prices in other countries were slightly above Swedish prices. The Swedish index has been relatively stable at just over 100 in 2015, 2016 and 2017.

For pharmaceuticals exposed to competition, i.e. those in the product-of-the-month system, the dynamics are great, and the Swedish substitution system has proven to be very effective when patents expire and when competition arises. In this context, the goal is to monitor development over time so that this dynamic can be maintained and to ensure low prices and good competition.

Within the segment ‘pharmaceuticals in the product-of-the-month system’, Swedish prices are among the three lowest. The Netherlands, Sweden and Denmark create a group of countries where the prices differ from other countries. These countries steer sales to a large extent to the cheapest product where there is a possibility of substitution. The differences between the countries are significantly greater than for pharmaceuticals not exposed to competition. Between 2014 and 2017, the Swedish prices decreased relative to all countries except Ireland and the Netherlands. During the study period, new products were continuously added to the ‘product-of-the-month system’ as competition arose when a pharmaceutical lost its patents. These products have contributed to a fall in Swedish prices compared with other countries. However, a deeper analysis of the new pharmaceuticals that entered the ‘product-of-the-month system’ shows that the Swedish system is poorer than that of other countries in relation to pharmaceuticals where substitutability do not work.
References


German Federal Institute for Drugs and Medical Devices (BfArM), AMNOG (Act on the Reform of the Market for Medicinal Products). http://www.bfarm.de/SharedDocs/Glossareintraege/EN/A/AMNOG.html

Government of the Netherlands (2016) speech by the Minister of Health, Welfare and Sport to the Speaker of the Dutch Parliament 29 January 2016 regarding the Medicines Policy


Henschke, C., Sundmacher, L. and Busse, R., (2013) Structural changes in the German pharmaceutical market: Price setting mechanisms based on the early benefit evaluation. [http://ac.els-cdn.com/S0168851012003326/1-s2.0-S0168851012003326-main.pdf?_tid=345e82d8-d96f-11e5-a3b0-00000aabof6b&acdnat=1456150914_3f581226846648e5e440000cefd23388](http://ac.els-cdn.com/S0168851012003326/1-s2.0-S0168851012003326-main.pdf?_tid=345e82d8-d96f-11e5-a3b0-00000aabof6b&acdnat=1456150914_3f581226846648e5e440000cefd23388)


International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Italy Pharmaceuticals. [https://www.ispor.org/HTARoadMaps/Italy.asp](https://www.ispor.org/HTARoadMaps/Italy.asp)

Interpharma, Price comparison with other countries. [http://www.interpharma.ch/faktenstatistiken/4492-price-comparison-other-countries](http://www.interpharma.ch/faktenstatistiken/4492-price-comparison-other-countries)


## Appendix 1: Dependencies between countries’ price baskets

### Table 22. Overview of dependencies in pricing (direct and indirect dependencies).

<table>
<thead>
<tr>
<th>Countries included in the study</th>
<th>Countries used as reference countries: BE BG CY DK EE FI FR GR IE IS IT LV LU MT NL NO PL PT RO SI SK SE TR UK DK SE NO CH DE AT TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>x</td>
</tr>
<tr>
<td>Denmark</td>
<td></td>
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<tr>
<td>Finland</td>
<td></td>
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<tr>
<td>France</td>
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<td>Greece</td>
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<td>Ireland</td>
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<td>Italy</td>
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<td>Portugal</td>
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<td>Hungary</td>
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<td>Austria</td>
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</tbody>
</table>

Note: Denmark, the UK and Sweden are the countries in the study that apply a pricing method other than international reference pricing.
Appendix 2: Description of the pricing systems used by the different countries

This section is intended to improve understanding of the pricing and reimbursement systems in the 20 countries analysed in TLV’s international price comparison. The section begins with a Nordic overview. This is followed by information on the other countries.

Sweden
TLV determines which pharmaceuticals should be included in the pharmaceutical benefits scheme. In 2016, the cost of pharmaceuticals in the benefits scheme amounted to approximately SEK 26.1 billion, AUP, including patient co-payments. The cost of prescription pharmaceuticals without benefit amounted to SEK 3.7 billion. In addition, the cost for pharmaceuticals for inpatient care, referred to as requisition pharmaceuticals, amounted to SEK 8 billion.

For pharmaceuticals with no generic competition, value-based pricing is applied. TLV’s assessments are based on an ethical platform with three basic principles:
- human dignity principle – healthcare should respect that all people are equal in value,
- need and solidarity principle – those with the greatest medical need should be entitled to more of the healthcare resources,
- cost-effectiveness principle – the cost should be reasonable from a medical, humanitarian and socioeconomic perspective.

For a pharmaceutical to be subsidised, a pharmaceutical company must first submit a reimbursement application to TLV. The agency then assesses factors such as how cost-effective the pharmaceutical is and whether it should be included in the pharmaceutical benefits scheme. The decisions are made by the Pharmaceutical Benefits Board, which is TLV’s board of experts.

Managed entry agreements
A managed entry agreement is a contract between the county councils and a pharmaceutical company, and may be one of several grounds used by TLV when deciding on pricing and reimbursement status. New pharmaceuticals are being introduced earlier and earlier, and some pharmaceuticals are sometimes associated with uncertainties regarding use and efficacy in clinical practice. When new pharmaceuticals drive cost increases, risk sharing through managed entry agreements linked to uncertainties regarding use and efficacy becomes an increasingly important tool for TLV and the county councils in their management of uncertainties. Refunds

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29 See, for example, TLV (2017e) TLV (2017f) and TLV (2017g).
through agreements ensure cost-effectiveness and can dampen cost increases for new pharmaceuticals. Managed entry agreements between county councils, pharmaceutical companies and TLV can thus enable use of a pharmaceutical even when there is significant uncertainty about its medical efficacy and cost-effectiveness.\(^{30}\)

Managed entry agreements also have the potential to be a powerful tool for creating price-competition which is lowering the costs within established pharmaceutical areas where no competition or downward pressure on prices has occurred for various reasons. One example is biologics, where price competition rarely arises despite the existence of biosimilars. In 2016, managed entry agreements have led to competition in the area of TNF-alpha inhibitors through the introduction of biosimilars.

At the end of the first half of 2017, there were 18 pharmaceuticals covered by current managed entry agreements. In addition to these, a further three managed entry agreements between county councils and companies relating to a number of hepatitis C medicines ceased to apply. The total cost for the pharmaceutical areas subject to managed entry agreements accounts for almost 15 percent of the total costs for pharmaceuticals in the benefits scheme (the total cost for 2016 is approximately SEK 28 billion).\(^{31}\)

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 and at high prices.

**Table 23. Pharmaceuticals subject to managed entry agreements quarter 1 2017.**

<table>
<thead>
<tr>
<th>Name</th>
<th>Substance</th>
<th>ATC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zytiga</td>
<td>abiraterone</td>
<td>L02BX03</td>
</tr>
<tr>
<td>Humira</td>
<td>adalimumab</td>
<td>L04AB04</td>
</tr>
<tr>
<td>Zykadia</td>
<td>ceritinib</td>
<td>L01XE28</td>
</tr>
<tr>
<td>Cimzia</td>
<td>certolizumab pegol</td>
<td>L04AB05</td>
</tr>
<tr>
<td>Exviera</td>
<td>dasabuvir sodium</td>
<td>J05AX16</td>
</tr>
<tr>
<td>Zepatier</td>
<td>elbasvir, grazoprevir</td>
<td>J05AX68</td>
</tr>
<tr>
<td>Xandi</td>
<td>enzalutamide</td>
<td>L02BB04</td>
</tr>
<tr>
<td>Enbrel and Benepali</td>
<td>etanercept</td>
<td>L04AB01</td>
</tr>
<tr>
<td>Repatha</td>
<td>evolokumab</td>
<td>C10AX13</td>
</tr>
<tr>
<td>Raxone</td>
<td>idebenone</td>
<td>N06BX13</td>
</tr>
<tr>
<td>Revlimid</td>
<td>lenalidomide</td>
<td>L04AX04</td>
</tr>
<tr>
<td>Viekirax</td>
<td>ritonavir, paritaprevir, ombitasvir</td>
<td>J05AX67</td>
</tr>
<tr>
<td>Entresto</td>
<td>sacubitril, valsartan</td>
<td>C09DX04</td>
</tr>
<tr>
<td>Sovaldi</td>
<td>sofosbuvir</td>
<td>J05AX15</td>
</tr>
<tr>
<td>Epclusa</td>
<td>sofosbuvir, velpatasvir</td>
<td>J05A</td>
</tr>
<tr>
<td>Mekinist</td>
<td>trametinib</td>
<td>L01XE25</td>
</tr>
</tbody>
</table>

*Source: TLV analysis.*

\(^{30}\) TLV (2017d).

\(^{31}\) TLV (2017c) p. 6
Risk sharing is managed within the framework of these managed entry agreements as a way of addressing uncertainties related to use and efficacy in clinical practice. Risk sharing also helps to ensure cost-effective use despite the uncertainties that exist (common, for example, in relation to cancer). Risk sharing can also manage the risk of major budget impact and thereby crowding out effects. An example of this are the costs for hepatitis C, which can be very extensive if the county council budgets had to be encumbered by set prices instead of the actual cost. This was especially the case when these pharmaceuticals were introduced. The managed entry agreements also create competition in the case of older biologics whose patent expired if equivalent biosimilars had been introduced to the market (TNF inhibitors). Downward pressure on prices and costs for this group of pharmaceuticals occurs through managed entry agreements and control of volumes via the county councils instead of via the product-of-the-month system.

In several cases, there are combinations of these elements in various agreements. The form that risk sharing takes depends on what uncertainties and market situation exist.

**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 2,200 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 are free of charge for children under the age of 18.

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

**Generic substitution**

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. 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.

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32 The level will be adjusted to SEK 2,250 beginning in 2018.
33 TLV (2017h).
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.\(^{34}\)

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, the county council covers the cost.

There is no VAT on prescribed pharmaceuticals (prescription pharmaceuticals or non-prescription pharmaceuticals obtained by prescription). Non-prescription pharmaceuticals are subject to VAT of 25 percent.

**Finland**

Finland has applied informal reference pricing since 2009. The system was introduced as a supplement to generic substitution. Initially, the reference countries consisted of the countries of the European Economic Area (EEA). In 2014, the reference countries were redefined as EU 27, Norway and Iceland. In addition to references prices, factors such as therapeutic value, benefit and price of similar products are taken into consideration.\(^{35}\)

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 maximum five years.\(^{36}\)

**Finland, product-of-the-month system with price variation**

Finland uses a product-of-the-month system similar to that used in the Netherlands, Sweden and Denmark. However, the supply period is three months instead of

\(^{34}\) TLV (2017i).
\(^{35}\) HILA (2017).
\(^{36}\) Kela (2016a)
one month like in Sweden. The price of other substitutable pharmaceuticals can be changed during the three-month period.\textsuperscript{37}

For generic pharmaceuticals in Finland, the first subsequent product for an original pharmaceutical is priced at least 50 percent lower than the original. The price of any subsequent generic pharmaceutical may not exceed the set price. For certain products, the level is 40 percent. One change introduced for original pharmaceuticals from 2016 is that the original price shall be reduced by 40 percent 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 the substitution period, pharmaceutical companies inform Kela of what prices are applicable at the start of the three-month period. The reference price is calculated based on the pharmaceutical companies’ price notifications by adding € 0.50 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.\textsuperscript{38, 39}

For the first two weeks of the three-month period, the price is the same as that communicated by the pharmaceutical company. 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.

Because of 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-month’.\textsuperscript{40}

**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. In 2016, the ceiling for co-payments amounted to €610.37. For

\textsuperscript{38} Kela (2016c).
\textsuperscript{39} Kela (2016a).
\textsuperscript{40} Kela (2017a).
2017, the ceiling was adjusted to €605.13. A stepped system for co-payments was introduced in 2016. This means that all patients over the age of 18 pay €50 before any subsidy is applied. They are divided into three categories of pharmaceutical subsidies. Basic compensation covers 40 percent of the pharmaceutical’s price or calculated reference price (22.5% of the benefits scheme cost). Lower special compensation covers 65 percent of the pharmaceutical’s price or calculated reference price (11 chronic diseases) (17.7%). Higher special compensation covers 100 percent (34 serious chronic diseases) (48.3%) but the patient then pays €4.50 each time the prescription is filled. The remaining 11.5% of the benefits scheme cost is attributable to payment of other subsidies.

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

### Norway

The Norwegian price of outpatient pharmaceuticals is set in relation to the price level in other countries through formal reference pricing. In Norway, the ceiling price for prescription pharmaceuticals is regulated by the Norwegian Medicines Agency. Norway’s reference countries are: Belgium, Denmark, Finland, Sweden, Ireland, United Kingdom (NHS), Germany, Netherlands and Austria. These countries were chosen because of geographical proximity. The system was implemented in 2002. The calculation is carried out 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 done regardless of whether the product is marketed under different names in the reference countries. The calculation uses the exchange rate for at least the past six months’ average according to the central bank of Norway (Norges Bank).

The timing of price reviews is predetermined and ongoing, 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 percent of the market.

**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.

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41 Kela (2017b).
42 Kela (2016b).
43 Kela (2016a) s. 85.
44 Norwegian Medicines Agency (2017a).
The price is decreased in steps depending on sales volume.\textsuperscript{45} When generic competition arises, the price of the original pharmaceutical is reduced by 35 percent when the patent expires. The second step in the model occurs six months after this. The maximum price is then 59 to 81 percent lower than the price of the original pharmaceutical at the time of patent expiry. The third step occurs 18 months after generic competition arose. The maximum price is then 69 to 90 percent 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.\textsuperscript{46}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|}
\hline
\textbf{Turnover before generic competition} & \textbf{Step 1} (immediate) & \textbf{Step 2} (after 6 months) & \textbf{Step 3} (after 18 months at the earliest) \\
\hline
Under MNOK 100 & 35\% & 59\% & Turnover > MNOK 15 69\% \\
\hline
Over MNOK 100 & 35\% & 81\% & Turnover > MNOK 30 88\% \\
\hline
& & & Turnover > MNOK 100 90\% \\
\hline
\end{tabular}
\caption{Trinnprismodellen/Norwegian stepped pricing model}
\end{table}

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

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 \textit{Byttelistan} (substitution list).\textsuperscript{47} If a patient does not accept generic substitution, they must pay the additional cost.\textsuperscript{48}

Since April 2017, there are managed entry agreements within outpatient care. Different agreements have been entered into for two products: Repatha and Praluent.\textsuperscript{49}

\textit{H-prescriptions}

In addition to the prescribing of common prescriptions, Norway 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 called Lekemiddelinkøbssamarberid (LIS). Like Amgros in Denmark, it works to obtain discounts on inpatient pharmaceuticals.

\textsuperscript{45} Norwegian Medicines Agency (2017b).
\textsuperscript{46} Norwegian Medicines Agency (2015).
\textsuperscript{47} Norwegian Medicines Agency (2017d).
\textsuperscript{48} Norwegian Medicines Agency (2017c).
\textsuperscript{49} Norwegian Medicines Agency (2017e) Oversikt over maksimalpriser. Vær oppmerksom på at dette er maksimalpriser og at faktisk pris derfor kan være lavere enn oppgitt. Dette gjelder for eksempel preparater med pasienttilgangsavtale (Repatha og Praluent); https://legemiddelverket.no/refusjon-og-pris/pris-pa-legemidler/maksimalpris#oversikt-over-maksimalpriser
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, clotting factors and growth hormones was transferred to inpatient care in 2016. 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.

**High-cost protection**

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

**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 assortment changes as often as every 14 days. The product with the lowest price in the respective group automatically becomes the highest compensation that is subsidised.

Products-of-the-month 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. Class C products that exceed the bagatelle limit must be substituted unless otherwise specified by the doctor or patient.

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50 Norsk Helseinformatikk (2016).
51 Norwegian Medicines Agency (2016a).
52 Norwegian Directorate of Health (2017).
53 Danish Medicines Agency (2017a).
54 COWI (2014). p.32.
The Danish Association of the Pharmaceutical Industry (Lif), the government and the regions in Denmark have entered into a price-capping agreement for pharmaceuticals.\textsuperscript{55} The first agreement covered the period 2012-2014. Since then, the agreement has been extended a number of times – first for the period 1 January 2015 to 1 July 2016 and then for the period July 2016 to December 2018.

On 1 April 2016, the Danish regions, the Danish Ministry of Health and the Danish Association of the Pharmaceutical Industry (Lif) entered into an agreement which specifies that the reference price model for list prices within inpatient care must undergo a conversion resulting in a 10-percent price reduction over a three-year period.\textsuperscript{56} The agreement runs 1 April 2016 - 31 March 2019. 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.

\textit{High-cost protection}

Pharmaceutical companies apply for benefits scheme status with the Danish Medicines Agency.\textsuperscript{57} 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 percent of the price. The general reimbursement is a positive list and can be limited to an indication group or a patient group.\textsuperscript{58}

The general reimbursement and co-payment thresholds are as follows 2017: 0 percent of the cost up to DKK 950, 50 percent of costs between DKK 950 and 1,565, 75 percent of costs between DKK 1,536 and 3,390, and 85 percent of costs over DKK 3,390. Co-payment is capped at DKK 3,955 per year. Children under the age of 18 are subject to different reimbursement thresholds than adults.\textsuperscript{59}

Since 2015, pharmacists are 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.

\textbf{Germany}

Germany applies a pricing and reimbursement system that combines free pricing, reference pricing and value-based pricing. The reference pricing component is informal/supporting, and price data is collected at the ex-factory level.\textsuperscript{60}

The majority of the German population (90\%) is covered by the statutory health insurance (SHI). The remainder of the population is covered by private insurance.

\textsuperscript{55} COWI (2014), p. 57.
\textsuperscript{56} Danish Ministry of Health (2016a).
\textsuperscript{57} Danish Medicines Agency (2017c).
\textsuperscript{58} Danish Medicines Agency (2017d).
\textsuperscript{59} Danish Medicines Agency (2017e). The maximum annual co-payment for children under the age of 18 is DKK 3,955. The reimbursement is 60\% for costs up to DKK 950, 60\% for costs between DKK 950 and 1,565, and 75\% for costs between DKK 1,565 and 3,390.
\textsuperscript{60} Silke Baumann and Karam Abulzahab contributed information for the description of the German system, 9 November 2017.
Private health insurance companies usually have the same products as SHI, but are able to limit or expand the benefits.

All approved pharmaceuticals that enter the German market are included in sickness funds unless they belong to a non-statutory category (e.g., OTC) or a decision against inclusion has been made by the Federal Joint Committee (Gemeinsamer Bundesausschuss – G-BA). The patients are generally obliged to contribute to the cost of pharmaceuticals through a co-payment of 10% (minimum €5 and maximum €10 per prescription).

The Act on the Reform of the Market for Medicinal Products (AMNOG), which entered into force on 1 January 2011, regulates the pricing of new pharmaceuticals. Under AMNOG, manufacturers freely set prices for pharmaceuticals at the time of market entry. At the same time, however, they must submit documentation with the data necessary to assess the therapeutic benefit of the pharmaceutical. AMNOG states that G-BA shall perform a formal assessment of the “additional therapeutic benefit” of new pharmaceuticals. The price is subject to negotiation based on the assessed therapeutic benefit within twelve months of the date the product is launched on the German market. The purpose of AMNOG was to limit rising pharmaceutical costs while retaining early access to new medicines and incentives for innovation.

Additional therapeutic benefit is assessed against a suitable comparator (standard of care) within 6 months. IQWiG (the Institute for Quality and Efficiency in Health Care) usually carries out the assessment. The decision (assessment) on additional therapeutic benefit is based on this assessment and the results of a public enquiry after publication of the evaluation. G-BA’s decision on additional therapeutic benefit determines the benefits scheme price after the first year with free pricing. If the pharmaceutical has not shown any additional therapeutic benefit, it is included in a reference price cluster. The manufacturer and the National Association of Statutory Health Insurance Funds (GKV-SV) negotiate a benefits scheme price within six months based on G-BA’s decision. If the parties cannot reach an agreement, the price is set through arbitration.

AMNOG’s evaluation and price negotiation apply to all new pharmaceuticals with new active substances introduced on the German market after 1 January 2011. Exceptions exist for pharmaceuticals with annual sales within SHI under €1 million. For orphan drugs, additional therapeutic benefit is assumed upon marketing authorisation without reference to a suitable comparator in Germany, provided that annual sales within SHI are below €50 million. If this threshold is exceeded, the orphan drug is evaluated, and the price is negotiated the same way as all other pharmaceuticals.

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61 VFA, How does a new drug enter the market?
62 66 pharmaceuticals were evaluated between 2011 and 2014, whereby 27 did not show any additional benefit over existing pharmaceuticals.
63 German Federal Ministry of Health, Die Spreu vom Weizen trennen Das Arzneimittelmarktnuordnungsgesetz (AMNOG).
64 German Federal Institute for Drugs and Medical Devices (BfArM), AMNOG (Act on the Reform of the Market for Medicinal Products).
There is no direct pricing for pharmaceuticals introduced prior to 2011. However, in relation to the generic market and the me-too market there are several instruments that affect (benefits scheme) prices for these pharmaceuticals and/or steer doctors towards more rational prescribing behaviour (e.g. towards prescribing a generic alternative).

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

Pharmaceuticals in a reference price cluster are assigned a maximum benefits scheme amount. If the price of the pharmaceutical exceeds the amount, the patients pay the difference. The companies usually reduce their prices to match the maximum amount for compensation. If they do not do this, patients can ask the prescriber for an alternative.

Discounts on the official price are common in the health insurance system, particularly for generic pharmaceuticals. Individual sickness funds can award discounted agreements 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 procurement organisations, with the official price for outpatient care serving as a ceiling price.

The pharmaceutical companies offer a discount of 7% off the list price for patented pharmaceuticals that are not grouped in reference price groups. There are also discounts for generic pharmaceuticals. A 6 percent discount is applied for pharmaceuticals exposed to competition outside of the reference price system. Generics and parallel imports are further discounted ten percent if the price is not at least 30 percent below the reference price.

The legislation also stipulates a price freeze on the price level that applied on 1 August 2009. It was extended to 2022. Beginning in 2018, prices can be adjusted for inflation.

Substitution at the pharmacy is an important tool for keeping down rising pharmaceutical costs. Pharmacy staff shall switch to a cheaper pharmaceutical with the same substance. If the patient’s sickness fund has an agreement on a discount for a product with the same substance compared to the prescribed product, the pharmacy

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65 The discount (ex-factory) through 2010 amounted to 6 percent for new, innovative pharmaceuticals. The discount for the category increased to 16 percent during the period 1 August 2010 - 31 December 2013. (KBV (2016) and Ruggeri, K. and Nolte, E. (2013) p. 42.)
In 2014, the decision was made to reduce the mandatory discount on subsidised pharmaceuticals from 16 percent to seven percent (Swedish Agency for Growth Policy Analysis (2016), p. 20.)

66 KBV (2016).
is obliged to dispense the product the discount regards. However, there are some therapeutic areas in which substitution is not permitted. Examples of these include thyroid hormones, anti-epileptic medicines and medicines for certain heart diseases. In all other cases, the prescriber can exclude substitution if medical reasons exist.

At the regional level, there are agreements between sickness funds and medical organisations regarding additional prescribing-related rules to hold back cost development and stimulate more rational prescribing behaviour, e.g. quotas for biosimilars. It is also possible to issue sanctions if doctors do not comply with these rules or other legislation.

Netherlands

Reference pricing to set the ceiling price is applied to all pharmaceuticals in both outpatient and inpatient care. The Netherlands has Belgium, France, Germany and the UK in its reference price basket. A price review takes place every six months, taking into account price changes in the reference countries as well as exchange rate changes. The official ceiling price is published twice a year.\(^67\) Internal reference pricing is carried out each month.

Since 2012, the Dutch Ministry of Health, Welfare and Sport can continue to set ceiling prices for pharmaceuticals, but is not obliged to do so.\(^68\) Since 2005, greater emphasis is placed 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.

Risk sharing agreements have become more common in the Netherlands in recent years. Such pharmaceuticals are usually managed within inpatient care, although there are risk sharing agreements 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.\(^69\) The purpose behind the change was that inpatient care (together with insurance companies) can act more powerfully as a procurer and thereby reduce the price. Hospitals also partner with each other to get discounts from manufacturers.

The healthcare system is publicly funded and operated through insurance companies. Since 2006, all Dutch citizens are required to have their own health insurance. The insurance companies act as the healthcare ‘buyer’. There are essentially two

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\(^{67}\) Medicijnkosten (2017).

\(^{68}\) There are several regulations in the Netherlands aimed at limiting and controlling government expenditures for prescription pharmaceuticals. Medicine Price Act (Wet Geneesmiddelenprijzen (WGP)) and reimbursement system (Geneesmiddelenvergoedingssysteem (GVS)).

\(^{69}\) In 2014, an insurance company partnered with 12 hospitals for the procurement of TNF-alpha inhibitors to keep costs down.

economic arrangements for health insurance; either the insurance company covers all costs when the prescriptions are filled, or the insured covers the initial expense and then submits a claim for compensation at the end of the insurance period.

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 ‘products-of-the-month’ at the pharmacies. A product becomes the preferred product when it has the lowest price within the pharmaceutical cluster. The product can then become the preferred product for a specific period of time, which varies between one and 24 months. However, some insurance companies apply an even longer period. The insurance companies apply different variants of preference policies 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.

Pharmaceuticals are prescribed by substance name (INN) instead of brand name. 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.\(^{70}\)

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 (the pharmaceuticals with high sales) dropped by about 90 percent.\(^{71}\)

In response to the price pressing effect of the tender process (which generated extra earnings for the insurance companies), the Dutch Ministry of Health, Welfare and Sport reduced the financial grant the state gave to the insurance companies in 2009. That same year, 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

Belgium has been using informal/supporting reference pricing since 2001. In 2014, it increased the number of reference countries from 24 to 27. 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 markups and margins are then set for distributors and pharmacies based on national regulation of both the margin (in percent) and the total maximum markup on distributor (wholesaler) purchase prices and within the pharmacy chain.

A general price reduction of all pharmaceuticals was carried out in April 2012. Manufacturers had to choose between lowering prices by 1.95 percent for all products or lowering prices on products of their choice to bring about the equivalent savings. In March 2015, a six-percent price reduction was implemented for pharmaceuticals in the reference price system whose cluster group had existed for at least six years. The price reduction affected almost all substances exposed to competition.

Generic pharmaceuticals are also subject to price regulation in Belgium. In March 2016, the pricing of generics was simplified. The price is reduced immediately when generics enter the market (in a reference cluster) rather than being incrementally reduced after two, four and six years. 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 percent lower (without reference cluster) or 51.52 percent lower (ex factory) depending on the reimbursement category.

With generic prescribing (INN), 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 that have expired patents but are not included in the benefits scheme are reviewed when one of the active substances in the combination drug is included in the benefits scheme. The price and degree of subsidy for the combination drug can never exceed the sum of the corresponding mono substances.

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

The United Kingdom applies indirect price control through an assessment of health economic aspects, e.g. cost effectiveness, and with regard to the pharmaceutical industry’s profitability. A study from 2014 shows that cost effectiveness weighs heavily in the assessment and was the single factor in explaining the outcome in 82 percent of NICE’s decisions.\(^72\)

In the UK, the pricing of original pharmaceuticals is regulated by a voluntary agreement with the pharmaceutical industry. Ceiling prices of original pharmaceuticals must be set so that they meet the voluntary Pharmaceutical Price Regulation Scheme 2014 (PPRS) agreement or other regulation.\(^73\) Prior to launch, pharmaceutical manufacturers must agree a maximum price with the Department of Health UK. New active substances according to European and national definitions are subject to free pricing. PPRS 2014 applies until 2018 and aims to provide stability in the pricing of original pharmaceuticals.\(^74\)

Reference prices, cost projections and clinical needs are taken into account when making pricing agreements. Monitoring of manufacturers’ profitability leads to the adjustment of prices and compensation levels. The monitoring of manufacturers regulates factors such as what proportion of government compensation should go to research and development, marketing, etc.

The pharmaceutical companies compensate the Department of Health based on a specific percentage of all pharmaceutical costs that exceed the agreed level. For 2017, the PPRS payment amounts to 4.75 percent.\(^75\)

Free pricing of generic pharmaceuticals applies in the UK provided that the pharmaceuticals are priced below the ceiling price applicable at the time of the original pharmaceutical’s patent expiry. Generic prescribing (INN) is voluntary, but is widely used.

Reimbursement is regulated through a negative list of pharmaceuticals which may not be prescribed with benefits. Most new pharmaceuticals are granted full reimbursement in connection with entry on the market and price approval.

France

France adopted formal/informal reference pricing in 2003. Prices (ex factory) shall be close to the prices in the reference countries (Germany, Spain, Italy and the UK). Reference price reviews take place every 60 months.

The pharmaceutical companies supply data on prices in other countries. The price that is determined is fixed for a period of five years, after which the list price can be

\(^72\) Dakin et al (2014).
\(^73\) Department of Health, UK (2014).
\(^74\) Department of Health, UK (2016) and Department of Health, UK (2017).
\(^75\) Department of Health, UK (2017). The payments have varied annually since the start in 2014. 3.74% for 2014, 10.36% for 2015 and 7.80% for 2016.
renegotiated. Reference pricing is not the main method used at the time of renegotiation.

Manufacturers wanting to launch a pharmaceutical with reimbursement must have it evaluated by the Economic Committee for Health Care Products (Comité Economique des Produits de Santé, CEPS). The transparency commission of the French High Authority for Health (Haute Autorité de Santé, HAS) assesses the therapeutic value of the pharmaceutical as well as the additional therapeutic value when compared with alternative treatments. The assessment scale has four steps, where 1 means great improvement, new therapeutic area, reduced mortality and 4 means no improvement. CEPS then negotiate the price with the manufacturer. Reference prices are only a part of the evaluation for pharmaceuticals assessed as 1-3 (great to some improvement). The pharmaceuticals are also subject to an HTA (Health Technology Assessment) evaluation.

In France, generic pharmaceuticals are priced at least 60 percent lower than the original. The price of the original is reduced by 20 percent, and then by an additional 12.5 percent 18 month thereafter. 18 months after the original pharmaceutical’s patent expires, the price of the generic is reduced by another 7 percent.

Biosimilars are priced at least 40 percent lower than the biological original. The price of biological originals are reduced by 20 percent. After 18-24 months, the price is further reduced based on the market share of the pharmaceutical. A market share of 60-100 percent results in a 15-percent price reduction. A market share of 40-60 percent results in a 10-percent price reduction. A market share of 0-40 percent results in a 5-percent price reduction.

Beginning 1 January 2015, generic prescribing (INN) is mandatory. However, it is also permitted to indicate a brand name on the prescription as an addition to generic prescribing.

The degree of subsidy depends on how the disease is classified: 100 percent subsidy for pharmaceuticals for severe chronic illnesses, 65 percent subsidy for pharmaceuticals with substantial clinical efficacy in relation to severe diseases, 30 percent subsidy for pharmaceuticals with lesser clinical efficacy, and 15 percent subsidy for pharmaceuticals with weak clinical efficacy.

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

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76 Pricing and Reimbursement Questions p. 43.
78 QuintilesIMS (2014).
Austria

Austria applies formal reference pricing. Price data 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 or pharmaceutical company sales price). Price review is carried out after six, 24 and 48 months from the pharmaceutical’s entry on 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. To calculate the average price, manufacturers need to provide information about the pharmaceuticals’ availability in other EU markets and state the prices in these countries.

Pharmaceuticals are categorised in different colour schemes for benefits: green, dark yellow, 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, essential, etc. are classed in the dark yellow category. In order for a reference price to be calculated, there must be price data 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.

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 percent within three months from the date a first generic enters the market. The first subsequent product is priced at least 28.6 percent lower than the original’s reduced price. The second subsequent product is priced 18 percent lower than the first subsequent one. If there is a third subsequent product, it is priced 15 percent lower than the second subsequent product. Thereafter, all comparable products must have the same price level as the third subsequent product within three months.79

For biosimilars, the price of the original product must be reduced by 30 percent after the first biosimilar enters the market in order to retain its benefits scheme status. The first biosimilar is priced at least 11.4 percent lower than the reduced price of the biological original. The second subsequent biosimilar is priced 15 percent lower than the first subsequent one. If there is a third subsequent biosimilar, it is priced 10 percent lower than the second subsequent biosimilar.80

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79 PPRI (2015a).
80 Herzig (2017).
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. Co-payment is capped at 2 percent of a patient’s annual income.

Ireland

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

On 20 July 2016, the Irish Government and the Irish Pharmaceutical Healthcare Association (IPHA) entered into a new framework agreement on pharmaceutical supply that is in force from 1 August 2016 through 31 July 2020. 38 pharmaceutical companies are part of the IPHA. Appended to the industry agreement are principles documents describing assessment of new pharmaceuticals. The agreement is expected to generate €600 million in savings during the period.

The agreement specifies that the price of pharmaceuticals must be set annually based on the average price in 14 reference countries. The reference price basket for price calculations and the annual adjustments has been expanded from nine to 14 countries, with Sweden, Portugal, Luxembourg, Greece and Italy being added to Austria, Belgium, Denmark, Finland, France, the Netherlands, Spain and the UK. The inclusion of a number of low-price countries is expected to lead to lower prices in Ireland. Germany was previously a reference price country, but has not been excluded since 2016.

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. Thereafter it is set for 1 July 2017, 2018 and 2019. Exchange rate changes 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 percent in sales value, an increase from 4 percent compared to 2016. The discount increases by 0.25 percentage points to 5.5 percent from 1 August 2018.

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81 Health Service Executive (2016).
82 Department of Health; Ireland (2016b).
83 Department of Health; Ireland (2016b), Schedule 2.
84 Department of Health; Ireland (2016).
85 Department of Health; Ireland (2016).
86 HSE (2016) IPHA Framework Agreement on the Supply and Pricing of Medicines 2016. http://www.hse.ie/eng/about/Who/cpu/IPHAprices16/ Further to the realignment of medicines as part of the IPHA Framework Agreement on the Supply and Pricing of Medicines 2016, the HSE is publishing the list of products whose prices have been revised effective 1 August 2016.
87 HSE (2017) IPHA Framework Agreement on the Supply and Pricing of Medicines 2017. http://www.hse.ie/eng/about/Who/cpu/IPHA-Price-Reduction-2017/ These price reductions are being carried out in accordance with the provisions of Clause 5.2 of the 2016 Framework Agreement on the Supply and Pricing of Medicines between IPHA, the Department of Health, the Department of Public Expenditure & Reform and the HSE.
The agreement also specifies a new discount for inpatient pharmaceuticals. It amounts to 5.25 percent of the sale value from 1 June 2016 and increases to 5.5 percent from 1 August 2018.

Ireland has introduced generic substitution at the ATC 5 level and reference pricing in order to reduce the total cost of pharmaceuticals. This reform was conditional to Ireland receiving aid under the EU/IMF financial assistance programme.

Generic pharmaceuticals are priced 50 percent below the price of original pharmaceuticals. When a generic pharmaceutical enters the market, the price of the original pharmaceutical is reduced by 30 percent within 60 days and by a further 20 percent the following year.\(^88\)

Biopharmaceuticals (Patent-Expired Non-Exclusive Biologic Medicine) are priced 20 percent below the previous price of the biological original. When a biosimilar enters the market, the pharmaceutical cost must decrease by a further 12.5 percent. This has been described as a rebate of a sum equal to 12.5 percent.\(^89\) It is unclear whether it is a rebate from the pharmaceutical company or the price is reduced for these pharmaceuticals.

There are essentially four systems for the benefits scheme.\(^90\)

- General Medical Services (GMS) – €2.50 co-payment per product and €25 per family and month.
- Drugs Payment Scheme (DPS) – ceiling for co-payment amounting to €144 per month.
- Long-term Illness Scheme (LTI) – 16 medical conditions have special coverage. The degree of subsidy amounts to 100 percent for persons.
- High Tech Scheme (HT) – pharmaceuticals dispensed at the pharmacy.\(^91\) Patient co-payment amounts to €62.03 when pharmaceuticals are collected at a pharmacy when dispensed and €30.26 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 €144 per month under the DPS.

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

**Italy**

Italy adopted formal/informal reference pricing in 2001. Reference pricing is not the main criterion, but it does support the decision-making process and is used in

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\(^88\) COWI (2014), p. 110

\(^89\) Section 8.1.3 in Framework Agreement on the Supply and Pricing of Medicines.

\(^90\) IPHA (2017)

\(^91\) High tech list February 2017 [http://www.hse.ie/eng/staff/PCRS/items/Feb%202017%20High%20Tech%20List- ing.pdf](http://www.hse.ie/eng/staff/PCRS/items/Feb%202017%20High%20Tech%20List-ing.pdf)
negotiations with the price committee. In negotiations with the price committee, issues taken into consideration include the following:92

- 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 data 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.93

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 within the range €1-8. There is no percentage degree of subsidy.

In Italy, generic pharmaceuticals are priced at least 20 percent 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 data 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-percent reduction of the maximum price for pharmaceuticals accepted in the benefits scheme was implemented. A price reduction of 7.5 percent was implemented in 2011, but only for specific biopharmaceuticals. Official list prices at that time were not to take account of that discount, according to Vogler et al 2011.

The subsidy is 100 percent for pharmaceuticals for specific defined diseases such as HIV and Alzheimer’s disease. For other prescription medicines, the level is 90 per-

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92 ISPOR Italy Pharmaceuticals.
93 ISPOR Italy Pharmaceuticals.
cent for critical pharmaceuticals for chronic diseases, 69 percent for critical pharmaceuticals for serious diseases, 37 percent for non-priority pharmaceuticals with therapeutic benefit, and 15 percent for new pharmaceuticals whose therapeutic benefit has not been established.

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

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

**Switzerland**

Switzerland applies formal reference pricing. The average price of pharmaceuticals in nine countries is used as reference. Price data is collected at the ex factory level. In 2015, the number of reference countries increased from six to nine through the addition of Belgium, Finland and Sweden. The other countries are Denmark, the Netherlands, France, Germany, Britain and Austria. The countries were chosen because they are considered similar in terms of economic conditions and pharmaceutical use structure.

Reference price is used in combination with national therapeutic comparison. 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). 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 percent that may be applied in the therapeutic comparison.

Prices are weighted with a 2/3 weighting for the international reference price and a 1/3 weighting for the national therapeutic comparison. There is a limit of five percent if the national therapeutic comparison gives a higher value than the international reference price. In the absence of data on international reference prices (for

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94 FOPH (2016a).
95 Interpharma, Price comparison with other countries.
96 FOPH (2016b).
97 FOPH (2016a).
example, if the pharmaceutical is not on the market in other countries), only the national therapeutic comparison is used.

The margin for distribution is regulated. For prescription pharmaceuticals it is CHF 4-240 plus a relative margin of 0-12 percent that is added to the ex-factory price.

When it comes to generic pharmaceuticals in Switzerland, the price must be at least 20 percent lower than the price of the original. 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 percent 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 CHF 4-8 million, the price is set 20 percent below that of the original. If the sales value of the original was CHF 8-16 million, the price is set 40 percent below that of the original. If the sales volume was CHF 16-25 million, the price is set 50 percent below that of the original. If the sales value exceeded CHF 25 million, the price of the subsequent product is set 60 percent lower than the original.

The price of biosimilars is set to 25 percent 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 percent of the remaining cost amounting to maximum CHF 700 per year is added to this. If a generic alternative to the medicine is available but not chosen, the patient’s additional cost instead amounts to 20 percent 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 data 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.

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98 FOPH (2016a).
Generics are obliged to enter the market at a discounted price to the original (after the patent expiry re-evaluation), depending on turnover of the original: 60% price discount, if turnover > CHF 25 mio. 50% price discount, if turnover > CHF 16-25 mio. 40% price discount. if turnover > CHF. 8-16 mio. 20% price discount, if turnover > CHF. 4-8 mio. 10% price discount, if turnover < CHF. 4 mio.
Prices for generic pharmaceuticals are set 40 percent 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 the INN.

During the first half of 2010, a discount of 7.5 percent on original pharmaceuticals and 4 percent on orphan drugs was implemented. Official list prices shall take account of this discount. At the same time, a 30-percent price reduction was also implemented for generic pharmaceuticals. A discount system 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. Since 2016, price review takes place twice a year, namely 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 are 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 percent lower than the original was prior to patent expiry. (It was previously 20 percent). Pharmaceuticals whose sales price does not exceed €4.5 and for which the patient’s daily 24-hour dose does not cost more than €0.15 are exempt from mandatory price reduction for generic pharmaceuticals (as per January 2017). From July 2017, the levels have been adjusted to sales price of less than €1 and a daily price of less than €0.02.

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 INN. 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.

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101 Previously, sales levels for exceptions were higher, e.g. the limits were €12 and €0.40 per daily dose in 2015.
Since 2016, patients and industry now share the cost between the excess amount and the cheapest pharmaceutical in the group. A limitation meaning that patients pay at most €20 extra per pharmaceutical has also been introduced. Previously, the limit was €50 extra per pharmaceutical.

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

**Hungary**

Hungary applies formal reference pricing using the lowest price of 31 countries (EU and EEA). Price data is collected at the ex-factory level. Reference price reviews take place each year for the products with the highest sales volume in the benefits scheme.

For generic pharmaceuticals in Hungary, the first subsequent product is priced at least 40 percent below the price of the original. The second subsequent generic product is priced 20 percent lower than the first subsequent product. The third subsequent product is priced 10 percent lower than the second subsequent product. The fourth through sixth subsequent product is priced five percent 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 percent lower than the price of the original, and the second and third product are priced 10 percent lower than this.\(^{102}\)

The degrees of subsidy are 85 percent, 55 percent and 25 percent depending on therapeutic value and the severity of the disease. For some specific diseases, a stepped subsidy up to 100 percent 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.\(^ {103}\) From 1 January 2018, Greece will no longer serve as a reference country.

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 percent lower than the second lowest price, the average of the second and third lowest price is calculated. Price data 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.

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\(^{103}\) SUKL (2017).
Pharmaceuticals deemed to be *highly innovative* can receive temporary reimbursement status for a two-year period, which can be extended 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 percent lower than the price of the original (15 percent for biopharmaceuticals, but an adjustment in 2017 changes this to 30 percent). The same lowest price reduction is applied to the entire reference group.

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).

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. Reference price reviews take place every 6 months. Price data is collected at the ex factory level.

Pharmaceuticals classified as new and innovative are investigated to see if their efficacy is equivalent to the limit set for quality-adjusted life years (QALYs). The limit is set at the average work income in Slovakia for the previous two years.

The degree of subsidy is either 100 percent or a partial amount depending on criteria.

Generic prescribing is 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 percent lower than the original (at least 20 percent for biosimilars).

**Poland**

Poland applies informal/supporting reference pricing using prices from 31 countries (EU and EFTA). Price data (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).

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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 percent. The degree of subsidy is 100 percent 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 percent of the reference price of the original. The first price decision applies for two years, and thereafter in three-year and five-year periods.