Copenhagen Economics

SAVINGS FROM PARALLEL IMPORT OF PHARMACEUTICALS IN FINLAND

2016 – 2020

Suppliers of Parallel Imported Medicines in Finland
May 2021

Introduction

The Suppliers of Parallel Imported Medicines in Finland have asked Copenhagen Economics to calculate savings from parallel imports of pharmaceuticals in Finland during 2016–2020. The calculations show direct and indirect savings in the pharmacy and hospital sectors. Additionally, we have determined the savings to taxpayers and patients, including forgone savings. Forgone savings mean savings that could have materialised if the most affordable parallel-imported medicine had always been chosen instead of the original product.

To calculate the savings in the pharmacy sector, we were able to draw upon data on historical prices and traded volumes provided by the Pharmaceutical Information Centre. As the data was provided on a confidential basis, we can only disclose results that cannot be traced back to any single product or company. Regarding savings in the hospital sector, we were able to draw upon information on competitive tendering made available by the Suppliers of Parallel Imported Medicines in Finland (Abacus Medicine, Paranova and Orifarm). Each company submitted its own data separately, and the data – or the findings based on the data not disclosed in this report – was not shared between the companies. The data on the hospital sector was provided by the hospital pharmacy responsible for each round of competitive tendering. The data includes the actual prices quoted in the tendering process. In this report, we have matched the price information obtained from the hospital sector with the sales data provided by the Pharmaceutical Information Centre.

Aside from the calculations, we interviewed five experts and researchers working within the field of pharmaceuticals.

We wish to express our thanks to the Suppliers of Parallel Imported Medicines in Finland, Abacus Medicine, Paranova and Orifarm for providing the data that formed the basis for this project and the calculations. The conclusions drawn in the report are exclusively those of Copenhagen Economics and do not necessarily reflect the opinions of the interviewees or partners. Copenhagen Economics is also responsible for the calculations and data processing.

Copenhagen Economics is an independent consultancy specialising in economics. Copenhagen Economics has prepared a similar report for the Danish Association of Parallel Importers of Pharmaceuticals. This report has been prepared jointly by the Danish and Finnish offices of Copenhagen Economics. This cooperation made it possible to draw upon the experiences gained from the previous report and combine it with the knowledge of local markets.

Stakeholders

Copenhagen Economics CE

The report was authored by Copenhagen Economics

ABACUS MEDICINE LÄÄKE TIETO KESKUS ORIFARM PARANOVA

The report is based on data provided by the Pharmaceutical Information Centre and customers

SUPPLIERS OF PARALLEL IMPORTED MEDICINES IN FINLAND

The report was sponsored by the Suppliers of Parallel Imported Medicines in Finland

1. Copenhagen Economics, (2019), The economic impact of parallel imports of pharmaceuticals: an assessment of savings in Denmark: https://www.copenhageneconomics.com/dyn/resources/Filelibrary/file/9/259/1579856365/200124_the-economic-impact-of-parallel-imports-of-pharmaceuticals.pdf

Johdon tiivistelmä

Suomen hallituksen tavoitteena on tehostaa lääkemarkkinoita ja saavuttaa siten säästöjä lääkekorvauksissa.[1] Lääkkeiden rinnakkaistuonti on yksi keino laskea lääkekorvausmenoja. Lääkkeiden rinnakkaistuontia on ollut EU:ssa 1970-luvulta lähtien. Rinnakkaistuodut lääkkeet ovat alkuperäisiä lääkkeitä, jotka tuodaan toisesta EU-maasta, jossa ne ovat edullisempia kuin Suomessa. Tästä johtuen ne ovat samoja lääkkeitä kuin alkuperäisvalmistajien lääkkeet.

Laskelmiemme mukaan lääkkeiden rinnakkaistuonnin kokonaissäästöt, ja hyödyt veronmaksajille sekä potilaille olivat 41 miljoonaa euroa vuosina 2016-2020.

Suomen Lääkerinnakkaistuojat ovat pyytäneet Copenhagen Economicsia arvioimaan lääkkeiden rinnakkaistuonnin säästöt Suomelle vuosina 2016-2020. Tämä raportti pohjautuu kahteen aineistoon, joista saamme kulutettujen lääkkeiden määrät ja niiden hinnat. Aineistot ovat Lääketietokeskuksen toimittama Pharmarket aineisto ja asiakkaidemme toimittama aineisto sairaaloiden lääkekilpailutuksista.

Lääkkeiden rinnakkaistuonti tuo säästöjä Suomessa

Arviomme mukaan lääkkeiden rinnakkaistuonnin säästöt Suomessa vuosina 2016-2020 olivat 41 miljoonaa euroa. Koska rinnakkaistuotujen lääkkeiden markkinaosuus oli noin 3%, arvioimme rinnakkaistuonnin keskimääräiseksi säästöksi 8%. Suurin osa lääkkeiden rinnakkaistuonnin säästöistä kohdistuu apteekkisektorille. Apteekkisektorin säästöt olivat 32 miljoonaa euroa huolimatta rinnakkaistuotujen lääkkeiden pienestä 2% markkinaosuudesta. Sairaalasektorilla säästöt olivat 10 miljoonaa euroa ja rinnakkaistuotujen lääkkeiden markkinaosuus 5,6%.[2]

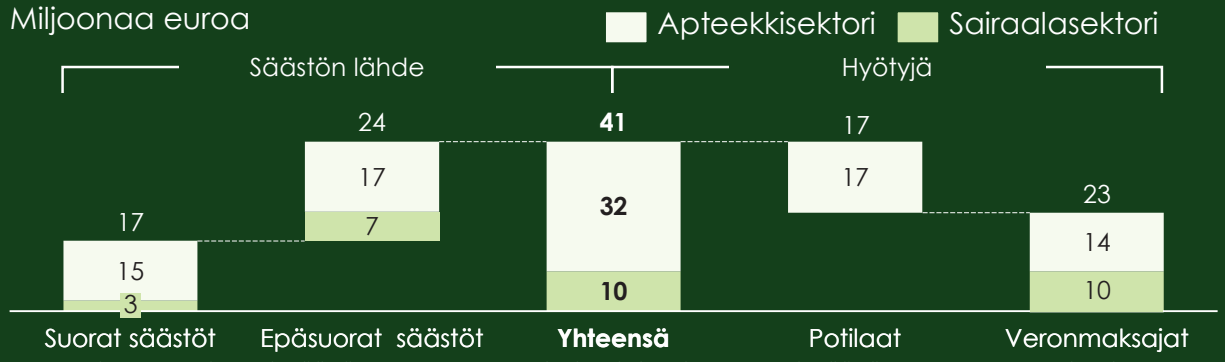
Lääkkeiden rinnakkaistuonnin säästöt syntyvät suorista ja epäsuorista säästöistä. Suorat säästöt, jotka syntyvät rinnakkaistuotujen ja alkuperäisvalmistajien hintaerosta, olivat 17 miljoonaa euroa. Epäsuorat säästöt, jotka syntyvät kun alkuperäisvalmistajat laskevat hintaa kohdatessaan kilpailua, olivat 24 miljoonaa euroa. Toisin sanoen, rinnakkaistuonnin luoma kilpailu laskee alkuperäisvalmistajien hintoja ja siten johtaa säästöihin.

Kokonaissäästöt hyödyttävät sekä potilaita, että veronmaksajia. Arviomme mukaan potilaat säästivät 17 miljoonaa euroa ja veronmaksajat 24 miljoonaa euroa, katso Kuvio 1.

Rinnakkaistuonnin säästöt voisivat olla merkittävästi suuremmat

Suorien ja epäsuorien säästöjen lisäksi arvioimme, että ns. ”menetetyt säästöt” olivat vuosina 2016-2020 noin 72 miljoonaa euroa. Nämä säästöt olisivat toteutuneet, jos potilaat olisivat ostaneet aina edullisimman rinnakkaistuodun lääkkeen myytyjen alkuperäislääkkeiden sijasta. Tulosten perusteella lääkkeiden rinnakkaistuonnin säästöissä on yhä kasvuvaraa. Rinnakkaistuonnin mahdollisiin säästöihin voidaan vaikuttaa muutoksilla sääntelyyn.

Kuvio 1. 41 miljoonan euron kokonaissäästöt säästön lähteen ja hyötyjän mukaan vuosina 2016-2020



Huomio: Apteekkisektorin säästöt on laskettu kuluttajahinnoin ja sairaalasektorin säästöt on laskettu tukkuhinnoin. Tulokset on pyöristetty lähimpään miljoonaan.
Lähde: Copenhagen Economics pohjautuen Lääketietokeskuksen ja asiakkaiden toimittamaan sairaalatarjouskilpailuaineistoon.

1. Hallituksen esitys eduskunnalle laeiksi sairausvakuutuslain, lääkelain 57 b ja 102 §:n sekä terveydenhuollon ammattihenkilöistä annetun lain 22 ja 23 §:n muuttamisesta
2. Markkinaosuudet pohjautuu Lääketietokeskuksen Pharmarket aineistoon. Markkinaosuudet ovat keskiarvoja vuosien 2016-2020 väliltä. Markkinaosuudet vuonna 2020 olivat 2,9% apteekkisektorilla ja 6,4% sairaalasektorilla.

Executive summary in English

The Finnish Government is determined to create efficiencies in the market for pharmaceuticals.[1] With this ambition in question, parallel imports (PI) of pharmaceuticals can be part of the answer. PI is the practice of importing pharmaceuticals from another EU country where they are cheaper than in Finland and the practice has been taking place since the 1970s. Hence, the imported pharmaceuticals are exactly the same medicinal products as those sold by the original manufacturers.

According to our calculations, the total savings from parallel imports of pharmaceuticals in 2016-2020 were €41m, benefitting both taxpayers and consumers of pharmaceuticals.

The Suppliers of Parallel Imported Medicines in Finland have asked Copenhagen Economics to calculate the savings from PI in Finland over the period 2016-2020. This analysis is based on two data sets containing volumes and prices of pharmaceuticals. More specifically, we employ Pharmarket data from the Medical Information Centre (the Pharmaceutical Information Centre) which we have supplemented with hospital sector tender results provided by Abacus Medicine, Paranova, and Orifarm.

Parallel importing of pharmaceuticals lead to savings

We estimate that the total savings from PI in 2016-2020 amounted to €41m. As the market share of PI in Finland was around 3% in 2016-2020, the average savings on PI were approximately 8%. Most of the savings, around €32m, occurred in the pharmacy sector, despite parallel importers' having a market share of only around 2%. In the hospital sector, where the share is approximately 5.6%, we estimate the corresponding savings to be around €10m.[2]

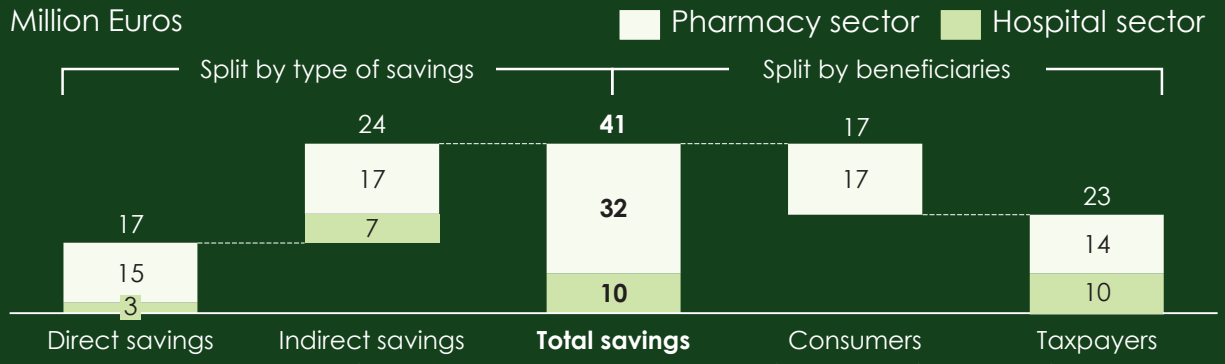
PI leads to direct and indirect savings. The direct savings can be measured and amount to €17m, which reflects the price difference between the parallel importers and the original manufacturers. The indirect savings are estimated and amount to €24m, which reflects the difference between the original manufacturer's estimated price without competition and the observed price in competition from parallel importers. In other words, the presence of parallel importers exerts a competitive pressure on the original manufacturers, leading to lower prices.

The total savings benefit both consumers and taxpayers. Consumers saved €17m due to lower co-payments in the pharmacy sector, and taxpayers saved €24m in both the pharmacy and hospital sectors due to lower prices, see Figure 1.

Forgone savings represent untapped potential

We find an additional and untapped potential of €72m in forgone savings in 2016-2020. This potential could have been realised if pharmacies had dispensed the cheapest PI alternative and if parallel importers had been able to supply the whole market. This result indicates a potential to increase savings from PI if regulation is revised and updated.

Figure 1. Savings of €41m from parallel imports of pharmaceuticals in 2016-2020 split by type of savings and beneficiaries



Note: The pharmacy sector savings have been calculated at consumer prices, and hospital sector savings at wholesale prices. The results have been rounded to the nearest million.

Sources: Copenhagen Economics, based on data from the Pharmaceutical Information Centre and hospital sector tender results.

1. Government proposal for acts to amend the Health Insurance Act, sections 57b and 102 of the Medicines Act, and sections 22 and 23 of the Act on Health Care Professionals
2. Market shares are 2016-2020 averages, based on Pharmarket data from the Pharmaceutical Information Centre. The parallel importers' market shares in 2020 were 2.9% in the pharmacy sector and 6.4% in the hospital sector.

Table of contents

1
PARALLEL IMPORTS OF PHARMACEUTICALS IN FINLAND

What is parallel import of pharmaceuticals?

Parallel import/parallel distribution is based on the free movement of goods within the EU internal market. Hence, it is consistent with the EU objectives for individual market areas. A parallel importer/distributor buys the original product in an EU/EEA member state in which the price level is more affordable, repackages the product and imports it into Finland. Thus, the medicine is identical to the original. All parallel-imported/distributed products are subject to authorisation by the Finnish Medicines Agency (Fimea) or the European Medicines Agency (EMA). We talk about parallel imports when the authorisation is issued by Fimea and parallel distribution when issued by EMA.[1] For the purposes of this report, we use the term parallel import (PI) to refer to both.

Parallel import occurs when parties other than original manufacturers make use of the differences in the price of pharmaceuticals across Europe. The price differences may be due to regulation, local differences in the purchasing power or different price-setting strategies applied by companies in individual countries.
Parallel imports tend to reduce prices as they compete with the pharmaceuticals supplied by original manufacturers. This effect is particularly pronounced when several operators engaged in parallel imports compete with one another.

Parallel imports of pharmaceuticals should not be confused with generic products. Usually, parallel imports consist of patented original products. Hence, parallel importers often compete with original manufacturers and one another. Generic manufacturing refers to a situation in which the patent on the original product has expired and a company other than the original manufacturer commences production based on the patent. Normally, when a patent expires and a generic product is introduced to the market, the price falls, which undermines profitability in the PI sector.

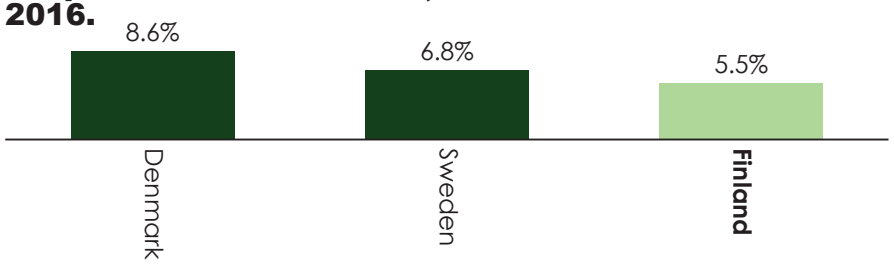
Parallel imports of pharmaceuticals modest in Finland

In Finland, the market share of PI pharmaceuticals is low, particularly when compared to Denmark and Sweden. In 2016, the market share of parallel imports was 5.5.% in the hospital sector and 0.9% in the pharmacy sector; see Figures 2 and 3.[2]

The modest market share of PI products in Finland has been explained by low wholesale prices, geographic location, lack of consumer awareness and by the fact that pharmacies have no financial incentives to sell more affordable pharmaceuticals.[2]

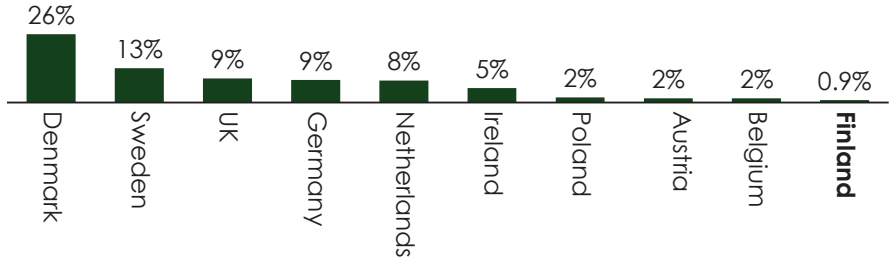
More information on parallel imports of pharmaceuticals is available on the websites of the Finnish Medicines Agency FIMEA and the Suppliers of Parallel Imported Medicines in Finland.[3]

Figure 2. Market share of parallel imports in the hospital sector in Finland, Sweden and Denmark in 2016.



Sources: Denmark – DLI-MI http://dli-mi.dk/, Sweden – Reveal market data, Finland - Pharmarket (Pharmaceutical Information Centre)

Figure 3. Market share of parallel imports in the pharmacy sector in European countries in 2016



Source: EFPIA; see efpia.eu/publications/data-center/the-pharma-industry-in-figures-economy/parallel-imports, Pharmaceutical Information Centre (pharmarket), see https://www.eduskunta.fi/FI/vaski/JulkaisuMetatieto/Documents/EDK-2016-AK-85779.pdf

1. Medicines Act section 21 d(16.10.2009/773)
2. We have used the 2016 market shares because they are comparable with the corresponding figures for the other countries. For comparison, the market shares in 2020 were 2.9% for the pharmacy sector and 6.4% for the hospital sector.
3. FIMEA: https://www.fimea.fi/myyntiluvat/rinnakkaistuonti, Parallel importers: http://laakerinnakkaistuojat.fi/

What is parallel import of pharmaceuticals?

While most of the expenditure on pharmaceuticals is spent in the pharmacy sector, the rate of increase is faster in the hospital sector.

Most of Finland's expenditure on pharmaceuticals is incurred in the pharmacy sector. It should be pointed out, however, that the rate of increase in costs is much higher in the hospital than the pharmacy sector. Hence, the savings offered by parallel imports of medicines may be expected to increase in the future, assuming that the market share of parallel imports and its rate of growth will not materially decrease.

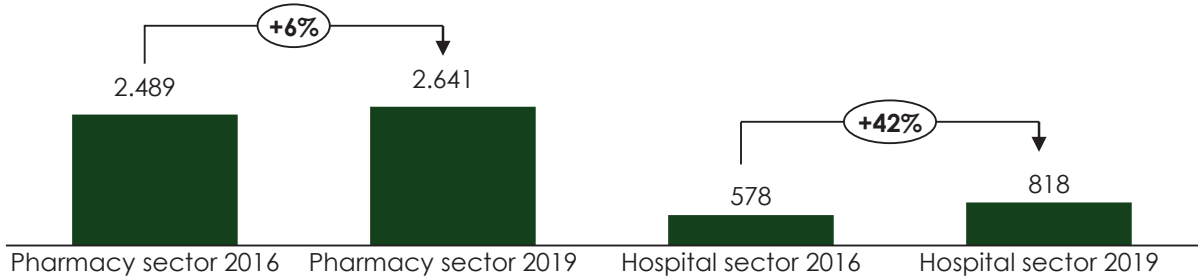
New medicines drive up costs in the hospital sector

The increase in the cost of medicines in the hospital sector has been noted in the public debate. According to some estimates, this is due to new pharmaceuticals placed on the market recently. New expensive products have been introduced, especially for the treatment of cancers, diabetes and the MS disease, which has increased the cost of hospital-dispensed medicines.[1] It should be pointed out that the estimate of the increased cost of hospital medication is based on wholesale prices in which the discounts offered by competitive tendering and risk-sharing agreements are not taken into account.

Since new medicines are protected by patents and cannot be manufactured as generic products, the potential offered by parallel imports for curbing expenditure on pharmaceuticals is substantial.

Figure 4. Sales of pharmacy and hospital-dispensed pharmaceuticals in Finland in 2016 and 2019

EUR million



N.B.: Euro-denominated sales in out-patient care are reported at retail prices, hospital sales at wholesale prices
Source: Finnish Statistics on Medicines for 2016 and 2019

1. Ministry of Social Affairs and Health (2020), "Lääkehoidon kokonaiskustannukset ja apteekkitalous – esiselvitys" (Pharmaceutical economy and the total cost of pharmacotherapy – Preliminary report)

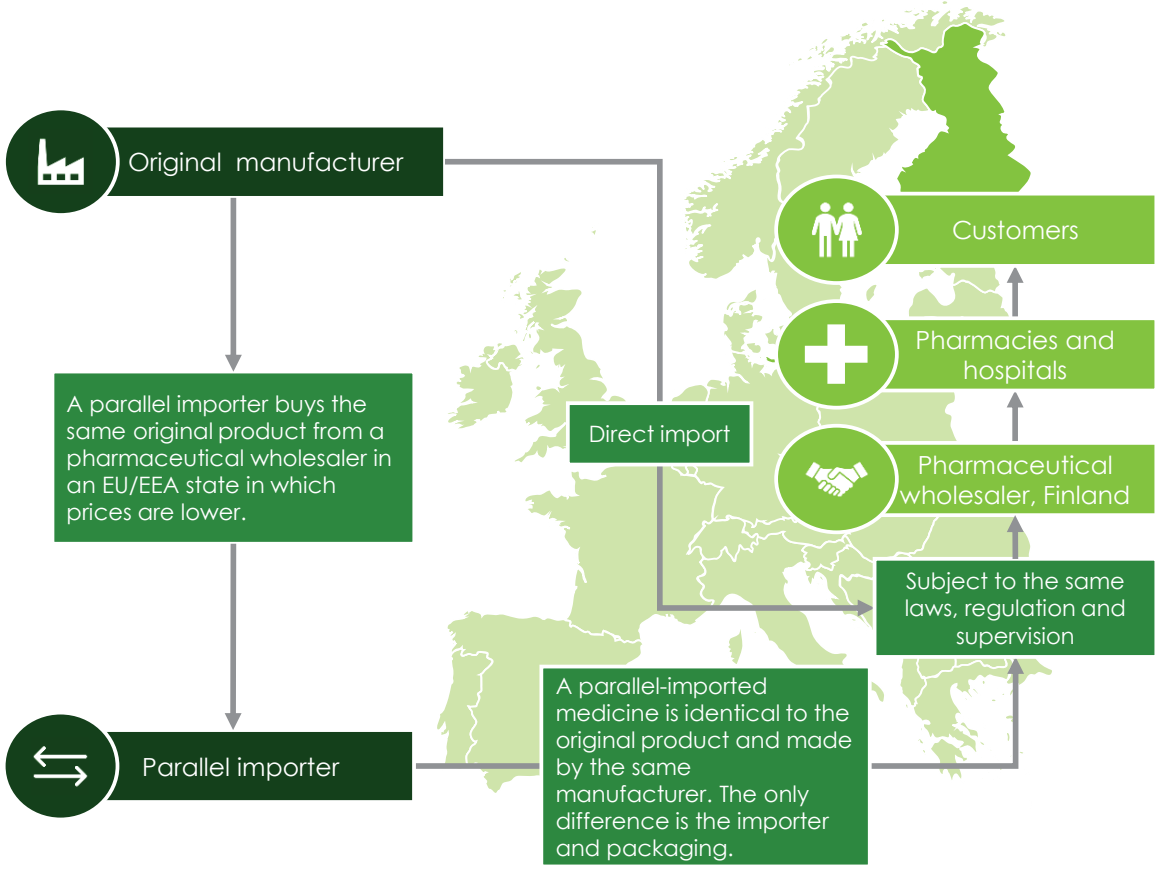
The value chain for parallel import of pharmaceuticals in Finland

When a patient in Finland buys a medicinal product in a pharmacy or receives it in a hospital, it may come from an original manufacturer or a parallel importer. Diagram 5 on the right illustrates how parallel imports work in reality.

Parallel import occurs when a parallel importer buys an original product in an EU/EEA member state in which the price is lower, repackages it and provides the packaging with Finnish texts and imports it into Finland. Since it is an original product purchased elsewhere, it is completely identical to the medicine made by the original manufacturer. The only differences are the importer, import package and price. Parallel-imported pharmaceuticals are subject to the same laws, regulations and supervision as other medicines.

Parallel importers acquire products throughout the EU/EEA territory depending on where the prices are the lowest and where the products are available in sufficiently large quantities. A necessary precondition for parallel imports is that the difference in wholesale prices between the two countries is big enough so as to make the activity profitable both for the parallel importer and the wholesaler in the target country.

Figure 5. Path of a PI product to the Finnish pharmaceuticals market



Source: Copenhagen Economics

Direct and indirect savings from parallel import

In this report, the savings from parallel import are broken down into direct and indirect savings. The principles for direct, indirect and overall savings from parallel import of pharmaceuticals are illustrated in Figure 6. A more detailed description of the principles and especially the assumptions underlying the calculations is provided in the Methodology section starting on page 27.

Direct and indirect savings

Direct savings mean savings that arise because the actual average prices of parallel-imported pharmaceuticals are lower than those of original products.

Indirect savings mean savings arising from competition on price. In other words, in the absence of competition from parallel imports, original manufacturers would charge higher prices. While indirect savings are just as real as direct savings, they involve a greater degree of uncertainty in terms of size, because no information is available on the prices that would be charged if there were no competition.

Pharmacy sector

We estimated the savings in the pharmacy sector by first determining the total expenditure on pharmaceuticals, assuming that all the products are purchased at the price of the original product. Next, we compared this figure with the actual pharmaceutical expenditure, i.e., the costs arising from the original and parallel-imported pharmaceuticals. By determining the difference between expenditure at the price of the original product and actual expenditure, we obtain the direct savings from parallel imports.
Indirect savings are calculated by comparing actual expenditure on pharmaceuticals with a situation in which all the pharmaceuticals would have been purchased at the price of the original products without any competitive pressure from parallel imports.
The calculations of the savings in the pharmacy sector and underlying assumptions are discussed in more detail in the Methodology section (pp. 27–33).

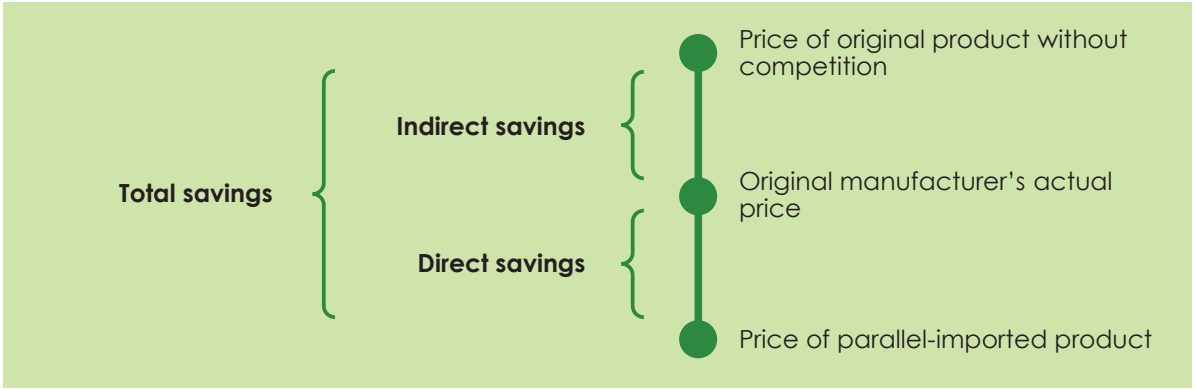
Hospital sector

We calculated the direct savings in the hospital sector by comparing the unit prices of parallel-imported medicines with the actual unit prices charged by original manufacturers. To determine direct savings, we multiplied the difference between the two by the volumes sold to hospitals.
Pharmaceutical sales in the hospital sector differ from those in the pharmacy sector in that hospitals always buy pharmaceuticals at a fixed price offered in competitive tendering. If the contract-winning pharmaceutical is not available, the company to which the contract was awarded is to compensate the difference between the price of the substitute product and the price quoted in the tender.

Indirect savings are calculated using the same method as in the pharmacy sector. In other words, we compare the expenditure on pharmaceuticals at the estimated price of the original product in the absence of competition with actual expenditure when PI products are available.

The calculations of the savings in the hospital sector and underlying assumptions are discussed in more detail in the Methodology section on pages 27–33.

Figure 6. Direct and indirect savings



Source: Copenhagen Economics

Forgone savings from parallel imports

Forgone savings

Aside from direct and indirect savings, we have estimated the forgone savings offered by parallel imports.

Forgone savings is a concept specifically developed for this report. Forgone savings mean savings that did not materialise but could have done so if the most affordable parallel-imported medicine had always been chosen instead of the original product. Forgone savings have only been determined for the pharmacy sector because hospitals only buy products at the price quoted in the winning tender.

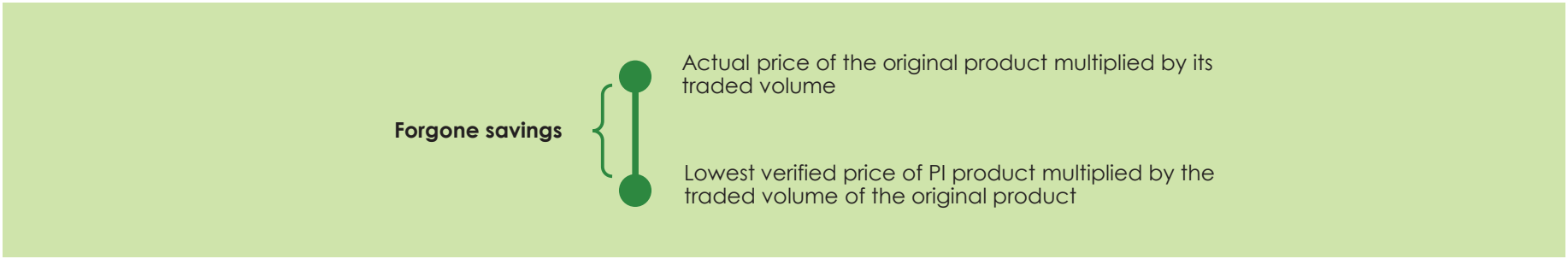
The principle of forgone savings potentially available through parallel importation is illustrated in Figure 7. A more detailed description of the principles and especially the assumptions underlying the calculations is provided in the Methodology section starting on page 27.

We assume that the most affordable parallel-imported product is always sold

To determine forgone savings, we have compared the expenditure on original products with a hypothetical situation, in which the total volume of the original pharmaceuticals would have been bought for the price of a cheaper parallel-imported product. Forgone savings have been determined for comparable medicinal products. In other words, forgone savings equal to the price difference arise whenever an original product is purchased instead of a comparable PI product.

To determine forgone savings, we made the following assumptions: (i) parallel importers are able to meet all demand; (ii) lower-priced PI products are always available to pharmacies; and (iii) customers always buy the more affordable PI product.

Figure 7. Forgone savings



Source: Copenhagen Economics

Previous studies on savings from parallel import of pharmaceuticals in Finland

No extensive research on parallel import of pharmaceuticals has been carried out in Finland. The most relevant studies we were able to find were by Linnosmaa, Karhunen and Vohlonen (2003)[1] and Koskinen, Kurko and Kuusisto (2017)[2]. The present report and earlier studies differ mostly in terms of the period of time covered by the data and partly also methodology.

As in this report, Linnosmaa, Karhunen and Vohlonen determined direct and indirect savings from parallel import of pharmaceuticals. Additionally, they also calculated potential savings which are not, however, directly comparable to the concept of forgone savings presented in this report. The authors estimated the savings from parallel imports during 1998–2001 at EUR 294,000.

The direct and indirect savings arrived at in said studies differ substantially from the findings of this report. Despite a similar methodology and research design, it is hard to compare the studies because the pharmaceutical market has, since then, seen significant amendments to the legislation that has increased competition between parallel importers and original manufacturers. For example, generic medicine substitution was introduced in 2003 and the reference price system in 2009. Moreover, the latter was updated as recently as 2017.

As a result of generic substitution, pharmacies are obliged to offer customers the most affordable substitutable product. Following the introduction of the reference price system, the maximum compensation payable to customers by the Social Insurance Institution of Finland (henceforth referred to by their Finnish title of "Kela") for reimbursable medicines was limited to the reference price. The 2017 reform to the reference price system further extended the formation of reference price groups. Before the legal amendment, PI medicines constituted a reference price group with the original products only if a generic product was also available on the market. After the legal amendment, a PI product could now form a reference price group with an original product on its own. The amendment is significant because PI medicines compete primarily with original products and other parallel-imported pharmaceuticals.

In the Kela research blog, Koskinen, Kurko and Kuusisto (2017) also looked into the savings offered by parallel-imported pharmaceuticals. At the beginning of 2017, they published a study on the impact of the 2017 legal amendment on competition on price. According to the report, price competition between the products included in the reference price system had reduced the price of pharmaceuticals to some extent. Kela's findings show that the average fall in the reference prices of pharmaceuticals in all the groups was 2.5 per cent at the beginning of April and 3.6 per cent at the beginning of July, when the latest price notification of the original manufacturer prior to the adoption of the reference price system (15 March 2017) is used as the benchmark price.

1. Linnosmaa, I., Karhunen, T. and Vohlonen, I., (2003). Parallel importation of pharmaceuticals in Finland. Pharmaceutical Development and Regulation, 1(1), pp. 67-74.
2. Koskinen, Kurko and Kuusisto (2017), Rinnakkaistuontivalmisteet viitehintajärjestelmään – hinnalla kilpailua vai paljon melua tyhjästä? (Inclusion of parallel-imported pharmaceuticals in the reference price system – competition on price or much ado about nothing?

Competition between parallel importers contributes to lower prices

We estimate that savings from parallel import of pharmaceuticals have been increasing particularly after 2017, when the reference price system was revised to allow PI products to form a reference price group together with the original product without generic products; see Figure 10. Aside from the renewal of the reference price system, a number of new parallel importers have entered the Finnish pharmaceuticals market, which has intensified competition. For example, Abacus and 2Care4 entered the Finnish market in 2018.

As already mentioned, parallel imports of pharmaceuticals increase competition and reduce prices. Competition on price is all the more efficient, the tougher the competition between parallel importers. If there is only one PI product on the market competing with the original product, it makes sense for the parallel importer to set the price of its product low enough to be competitive. To be able to do so, the parallel importer must know the prices charged by original manufacturers. In the pharmacy sector, here prices are updated every two weeks, parallel importers have a clear idea of the original manufacturers' prices. As a result, parallel importers are able to set their product prices within the reference price group below those of the original manufacturers. A similar price transparency exists in the hospital sector where the prices quoted by the competition are disclosed to all suppliers participating in competitive tendering.

Earlier studies provide empirical evidence showing that savings can be achieved from parallel import of pharmaceuticals only if there is competition between parallel importers.[1] In Finland, there are four parallel importers covering the entire market for PI pharmaceuticals in the country. The presence of four large importers means that they often compete with one another when contracts are put out to open tender. At the same time, this competition means that individual parallel importers have an incentive to undercut the prices of other importers in order to be competitive. Such a price may be substantially lower than that of an original product.

1. London School of Economics (2004), The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis

EUR 41 million in savings in the expenditure on pharmaceuticals during 2016–2020

From 2016 to 2020, total savings from parallel import of medicines amounted to EUR 41 million. Most of this, EUR 32 million, came from pharmacy-dispensed medicines. The rest of the savings were made in hospital medicines.

These aggregate savings of EUR 41 million account for 0.3% of Finland's total pharmaceutical expenditure of EUR 16.4 billion during 2016–2020. In view of total expenditure, the savings are modest, which is partly explained by the low market share of PI pharmaceuticals in Finland. Savings arise because PI pharmaceuticals are, on average, 8% less expensive than original products, compared to a situation in which there would be no parallel import and resultant competition with original products in Finland.

As already mentioned, the market share of PI pharmaceuticals in Finland is modest relative to many other EU Member States. Overall, PI pharmaceuticals held an average market share of 3% in Finland during 2016–2020. A closer analysis shows a market share of 2% in the pharmacy sector and 5.6% in the hospital sector over the same period. In the hospital sector, savings from parallel import of pharmaceuticals inure directly to the benefit of taxpayers because patients do not pay for hospital-dispensed medicines directly. By contrast, savings in the pharmacy sector benefit both taxpayers and patients because they pay part of the cost themselves. Savings benefitting taxpayers occur when the reimbursement payable by Kela decreases as a result of declining pharmaceutical costs. When calculating the savings, we gave due consideration to the fact that lower medicine prices also reduce total tax revenues on value added and pharmacy taxes.

Table 1. Savings from parallel import of pharmaceuticals in Finland during 2016–2020

		Pharmacy pharmaceuticals	Hospital pharmaceuticals	Total
Total pharmaceutical expenditure (EURm)	A	12.772	3.583	16.355
Market share of parallel importers (%)	B	2.0%	5.6%	3.0%
Direct savings from parallel import (EURm)	C	15	3	17
Indirect savings from parallel import (EURm)	D	17	7	24
Total savings from parallel import (EURm)	**E = C+D**	**32**	**10**	**41**
Average savings from PI pharmaceuticals (%)	F = E/(A*B+E)	11%	5%	8%
Total PI savings as percentage of actual pharmaceutical expenditure (%)	G = E/A	0.3%	0.3%	0.3%

N.B.: The savings in the pharmacy sector are calculated at consumer prices. Calculations take into account lower tax revenues on value added and pharmacy taxes due to the lower prices of pharmaceuticals. The savings in the hospital sector are calculated at wholesale prices. The results are rounded to the nearest million.
Sources: Copenhagen Economics based on hospital tendering data provided by the Pharmaceutical Information Centre and customers

2
SAVINGS IN THE PHARMACY SECTOR

Price-setting and regulation in the pharmacy sector

The Pharmaceuticals Pricing Board sets a reasonable wholesale price for medicines eligible for reimbursement

The Pharmaceuticals Pricing Board always sets a reasonable wholesale price for medicines eligible for reimbursement. Pharmaceuticals suppliers cannot set a higher price if they wish to remain in the reimbursement system. As a rule, the set prices are based on equivalent pharmaceuticals or the prices charged in other countries.

Since the reasonable wholesale price puts a ceiling on the maximum price, it probably limits the potential offered by parallel imports because regulation diminishes the price differences between Finland and other countries.

Generic substitution obligates the prescriber and pharmacy to offer the most affordable product

Pursuant to the Act on the substitution of medicines, the prescriber of the medicine must inform the patient that a substitutable medicinal product can be swapped for an equivalent less expensive product. Similarly, pharmacies are duty-bound to recommend the cheapest substitutable product for the customer.[2] The Act on substitution that entered into force in 2003 only applies to prescription medicines.[3]

The reference price system gives an incentive to choose more affordable pharmaceuticals

The reference price system was introduced in 2009. Under the reference price system, the maximum reimbursement payable by Kela for reimbursable medicines is based on the reference price, which is at most 50 cents higher than the price of the cheapest medicine in the group. A patient who declines to change medicines is required to pay the portion exceeding the reference price. A patient receives compensation for the full price of the medicine if the doctor has forbidden substitution or the indication is epilepsy or an atypical indication of an original product belonging to an atypical reference price group.[3]

In the reference price system, a reference price group consists of pharmaceuticals containing the same medicinal substances identical in composition and supplied in similar package sizes. The reference price groups are based on the list of interchangeable pharmaceuticals prepared by the Finnish Medical Agency. The reference price system was updated in 2017. Before the legal amendment, a PI product and original product were not enough to constitute a reference price group; there also had to be a generic product in the group.[4]

Under the reimbursement system, part of the cost of medicines is borne by taxpayers.

Patients receive reimbursement for the cost of prescription nutrients and basic lotions prescribed for the treatment of a medical condition. The medicine reimbursement system contains three categories. The basic reimbursement category, lower special reimbursement category and higher special reimbursement category. The reimbursement rates for the categories are 40%, 65% and 100%, respectively. Additionally, there are medicines that are not eligible for any reimbursement. Most of the medicines dispensed in out-patient care are eligible prescription drugs.[5] Medicine reimbursement expenditure is paid out of the government budget, and so ultimately by taxpayers. Decisions on eligibility for reimbursement are made by the Pharmaceuticals Pricing Board (Hila) under the auspices of the Ministry of Social Affairs and Health.

Consumer price of medicines based on the medicine tariff and value added tax

The price of medicines dispensed by pharmacies consists of the medicine tariff and value added tax. The medicine tariff is determined from the wholesale price. The amount of the medicine tariff is based on the wholesale price and whether the product is a prescription product or not. Value added tax is added to the price after medicine tariff. For prescription medicines, a service fee of EUR 2.39 applies. It should be pointed out that pharmacy tax is levied on the medicine tariff and is not added to the consumer price. Consequently, it has no impact on the final price.[6]

Substitution for a cheaper medicine not always possible despite regulation

Generic substitution and the reference price system do not guarantee that the cheapest medicine is always selected. A report by the Finnish Competition and Consumer Authority on the pharmacy market highlighted the problem that the cheapest medicines are not always stocked by pharmacies and that the incentives available to pharmacies do not encourage them to offer the least expensive substitutable product. Because of the medicine tariff system, pharmacies earn a higher absolute margin on more expensive pharmaceuticals.[7] To make medicine substitution work, it would be important to have effective incentives in place.

1. Based on background interviews conducted by Copenhagen Economics. 2. Medicines Act, section 57 (10.12.2020/1112). 3. Ministry of Social Affairs and Health Decree on the Prescription of Medicines, section 17 (22.12.2016/1459) 4. Social Insurance Institution Kela, Generic substitution and reference price system: https://www.kela.fi/laakkeet_laakevaihto-ja-viitehintajarjestelma, 5. Social Insurance Institution Kela, Reimbursements for medicine expenses: https://www.kela.fi/selkosuomi/laakekorvaukset, 6. Government Decree on medicine tariff: 17.10.2013/713 , 7. FCCA (2020), Apteekkimarkkinoiden kehittäminen (Development of the pharmacy market): https://www.kkv.fi/kkv-suomi/julkaisut/selvitykset/2020/kkv selvityksia-5-2020-apteekkimarkkinoiden-kehittaminen.pdf

Savings from parallel imports in the pharmacy sector

Total savings in the pharmacy sector EUR 32 million

According to our calculations, total savings from parallel import of pharmaceuticals in the pharmacy sector amounted to EUR 32 million during 2106–2020; see Figure 8.

We have eliminated generic products where possible in order to only determine savings derived exclusively from parallel imports.

Direct savings EUR 15 million

According to our calculations, the direct savings from parallel imports during 2016–2020 were EUR 15 million. The savings show how much more patients and taxpayers would have had to pay in the absence of parallel imports; see Figure 9.

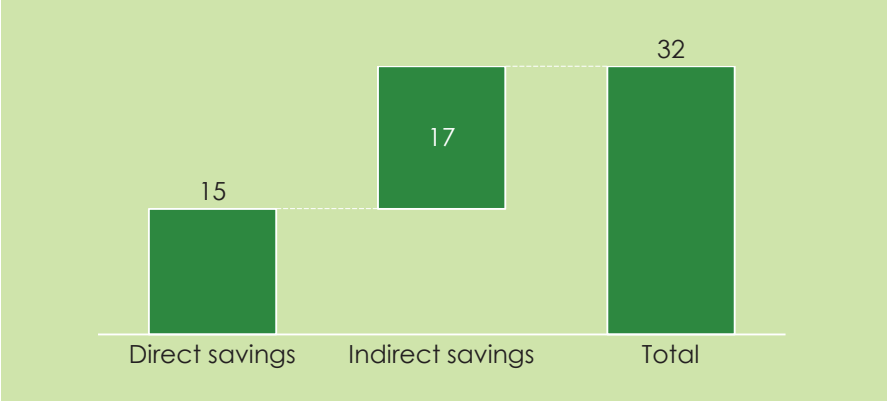
Indirect savings EUR 17 million

Aside from direct savings, parallel import of pharmaceuticals also generate indirect savings. These indirect savings arise when competition from parallel imports reduces the general price level of originally produced medicines. According to our calculations, indirect savings in the pharmacy sector during 2016–2020 amounted to EUR 17 million.

We did not determine other indirect savings for products in which parallel importers do not compete with original manufacturers. Theoretically, a mere possibility of competition may lower the prices of originally produced items in the affected groups of medicines.

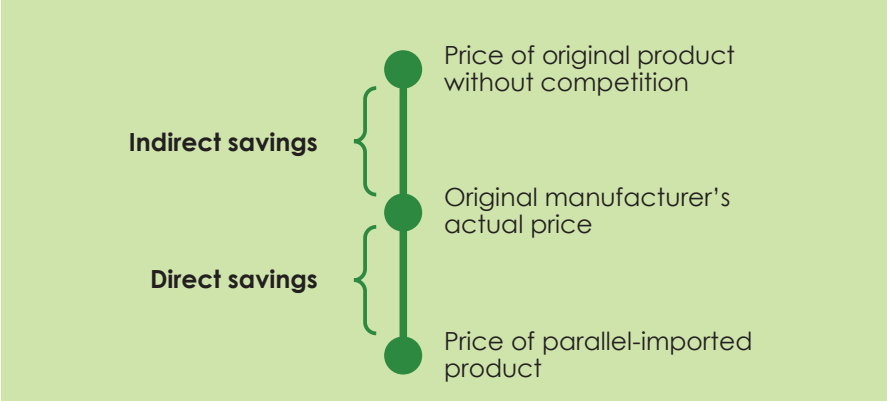
Figure 8. Savings from parallel import in the pharmacy sector during 2016–2020

EUR million



N.B.: The savings in the pharmacy sector are calculated at consumer prices. Calculations take into account lower tax revenues on tax revenues on value added and pharmacy taxes due to the lower prices of pharmaceuticals.
Source: Copenhagen Economics based on data provided by the Pharmaceutical Information Centre

Figure 9. Prices used in the calculations on the pharmacy sector



N.B.: We used the reasonable wholesale price set by the Pharmaceuticals Pricing Board converted into consumer prices as well as the first observed price of the product when no reasonable wholesale price was available.
Source: Copenhagen Economics

Annual savings from the parallel import of pharmaceuticals in the pharmacy sector

Savings in the pharmacy sector increasing year-on-year

Savings from parallel import of pharmaceuticals increased from EUR 2 million in 2016 to about EUR 12 million in 2020.

Most likely, the increase is due to the revision of the reference price system in 2017. It should also be pointed out that the growth is partly explained by the methodology used in this study to estimate indirect savings. When determining indirect savings, we used the price of original products with and without competition. For reimbursable medicines, we used the reasonable wholesale price set by the Pharmaceuticals Pricing Board as the 'price without competition' whereas for non-reimbursable medicines, we used the first observed price of the original product for this purpose. Since the first observed prices relate to the first few years of the period covered by the data, indirect savings are also lower in these years. It should be pointed out that because some of the non-reimbursable medicines did actually face competition from parallel imports, our estimate of indirect savings is conservative. To put it differently, the growth figures are partly explained by the fact that we underestimated the indirect savings achieved over the first few years. More on this in the Methodology section, see page 27 onwards.

Major increase in indirect savings during 2016

From 2016 to 2020, indirect savings increased from a few hundreds of thousands of euros to EUR 8 million. Direct savings too have grown but more steadily. The savings were EUR 2 million in 2016 and EUR 4 million in 2020; see Figure 10.

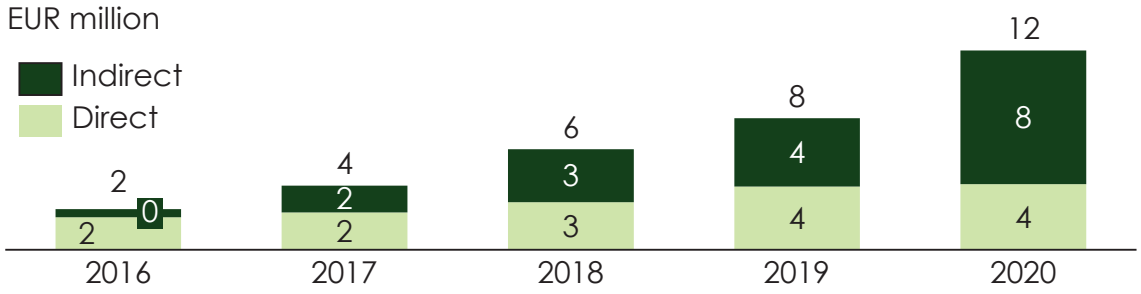
Most likely, the increase in savings is due to the revision of the reference price system

The 2017 reference price reform probably paved the way for the increase in savings during 2016–2020. For example, Kela's research blog (2017) shows that the inclusion of a larger percentage of PI products in the reference price system reduced medicine prices. The fall in prices was naturally reflected in savings.

The price-reducing effect of the reference price system is two-fold. First, the inclusion of PI pharmaceuticals in the reference price system together with just original products gave customers a financial incentive to substitute medicines. Second, the legal amendment improved the efficiency of substitution, thereby creating more favourable conditions for competition. Abacus and 2Care4 entered the Finnish market after the reform to the reference price system.

As a result of the reform, PI medicines can constitute a reference price group singly with an original product without any generic product. Now patients have a real financial incentive to swap medicines for less expensive PI products because the maximum reimbursement paid by Kela is based on the reference price. The reform to the reference price system is probably one reason why original manufacturers have lowered prices in order to be included in the reference price band[1].

Figure 10. Annual direct and indirect savings in the pharmacy sector



N.B.: The savings in the pharmacy sector are calculated at consumer prices. Calculations take into account lower tax revenues on taxes due to the lower prices of pharmaceuticals.
Source: Copenhagen Economics based on data provided by the Pharmaceutical Information Centre

1. The reference price band is formed around the most affordable medicine in the reference price system. The upper limit is 50 cents higher than the lowest-priced product.

Annual savings from parallel imports of pharmaceuticals in the pharmacy sector

Most materialised savings derived from reimbursable medicines

Figure 11 shows direct savings in the pharmacy sector for reimbursable and non-reimbursable medicines. As the figure shows, direct savings in non-reimbursable medicines have remained constant from 2016 to 2020. By contrast, direct savings in reimbursable medicines have grown.

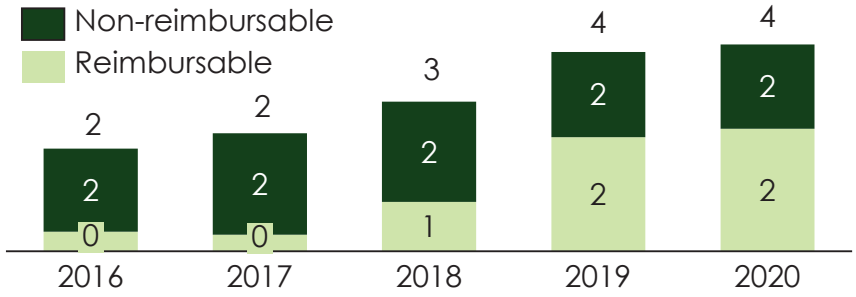
Figure 12 shows the indirect savings achieved in the pharmacy sector. Unlike direct savings, indirect savings increased for both reimbursable and non-reimbursable medicines. Of the two, the increase has been faster in reimbursable medicines. As far as the indirect savings in non-reimbursable medicines are concerned, it should be pointed out that the Pharmaceuticals Pricing Board sets no reasonable wholesale prices for these products. For this reason, we have used the first observed price of the original product as the 'price without competition'. A natural outcome of this is that the savings made in the first few years of the period were underestimated. Since parallel imports occurred even before 2016, it is safe to assume that the first observed prices in 2016 do not fully reflect the original manufacturers' prices without competition.

Reform to the reference price system affects reimbursable medicines

As already mentioned, savings in pharmaceutical expenditure have increased particularly in reimbursable medicines. This is only natural because the reference price system only includes reimbursable products. Similarly, the 2017 reform to the reference price system only applies to reimbursable medicines.[1] The introduction of a larger number of PI medicines into the reference price system has given customers a more powerful incentive to swap medicines for more affordable PI products because the reimbursement payable by Kela is based exclusively on the reference price.

Figure 11. Direct annual savings in the pharmacy sector for reimbursable and non-reimbursable medicines

EUR million

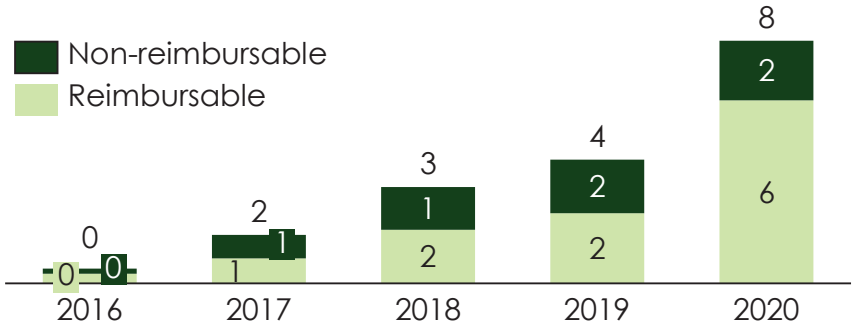


N.B.: The savings in the pharmacy sector are calculated at consumer prices. Due consideration is given to reduced tax revenues on value added and pharmacy taxes due to the lower prices of pharmaceuticals.

Source: Copenhagen Economics based on data provided by the Pharmaceutical Information Centre

Figure 12. Indirect annual savings in the pharmacy sector for reimbursable and non-reimbursable medicines

EUR million



N.B.: The savings in the pharmacy sector are calculated at consumer prices. Due consideration in the calculations is given to reduced tax revenues on value added and pharmacy taxes due to the lower prices of pharmaceuticals.

Source: Copenhagen Economics based on data provided by the Pharmaceutical Information Centre

1. Kela – reference price system: https://www.kela.fi/korvattavat-valmisteet_viitehintajarjestelma

Savings to patients and taxpayers from parallel imports of pharmaceuticals in the pharmacy sector

Savings in the pharmacy sector have mostly benefitted patients

Most of the savings in the pharmacy sector from parallel import of pharmaceuticals have benefitted patients. As a result of parallel imports, patients saved around EUR 17 million during 2016–2020. Savings to taxpayers over the same period amounted to EUR 14 million.

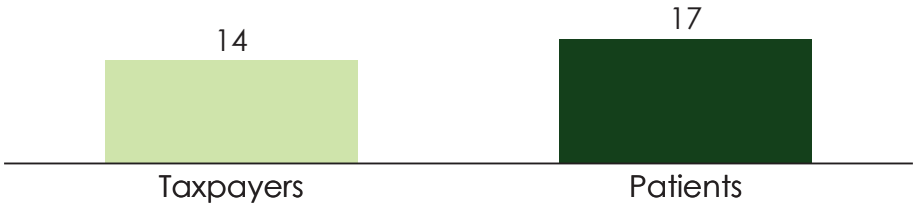
The method used to break down the savings to patients and taxpayers, respectively, is discussed in more detail in the Methodology section; see page 31.

Savings to taxpayers increasing at a faster rate than savings to patients

We estimate that savings to patients and taxpayers from parallel import of pharmaceuticals increased from EUR 2 million in 2016 to EUR 12 million in 2020. While savings to patients have been increasing steadily, those to taxpayers have increased slightly more, relatively speaking.

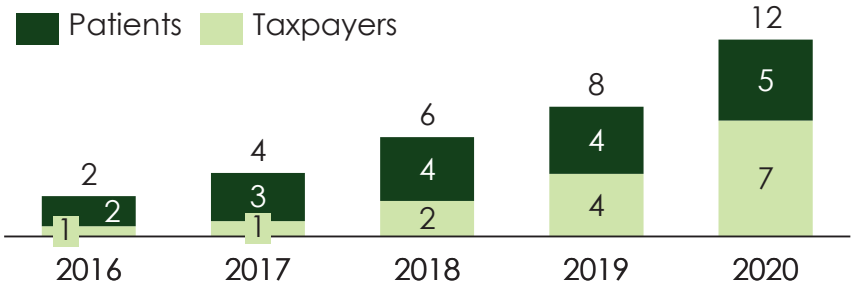
Since the reference price system only covers reimbursable medicines, it is only natural that savings to taxpayers have grown at a slightly faster rate after the 2017 reform to the reference price system.

Figure 13. Savings to patients and taxpayers from parallel import of pharmaceuticals during 2016–2020
EUR million



N.B.: Savings in the pharmacy sector are calculated at consumer prices and savings in the hospital sector at wholesale prices. The results are rounded to the nearest million.
Source: Copenhagen Economics based on hospital tendering data provided by the Pharmaceutical Information Centre and customers

Figure 14. Annual savings to taxpayers and patients in the pharmacy sector
EUR million



N.B.: Savings in the pharmacy sector are calculated at consumer prices with due regard to the reduced tax revenue due to lower medicine prices.
Source: Copenhagen Economics based on data provided by the Pharmaceutical Information Centre

Forgone savings from parallel imports in the pharmacy sector

This section provides an estimate of forgone savings in the pharmacy sector. Forgone savings mean savings that did not materialise but could have done so if the most affordable parallel-imported medicine had been purchased instead of the original product. Since forgone savings are not actual savings, we have not included them in the total savings from parallel imports.

Most forgone savings arise from non-reimbursable medicines

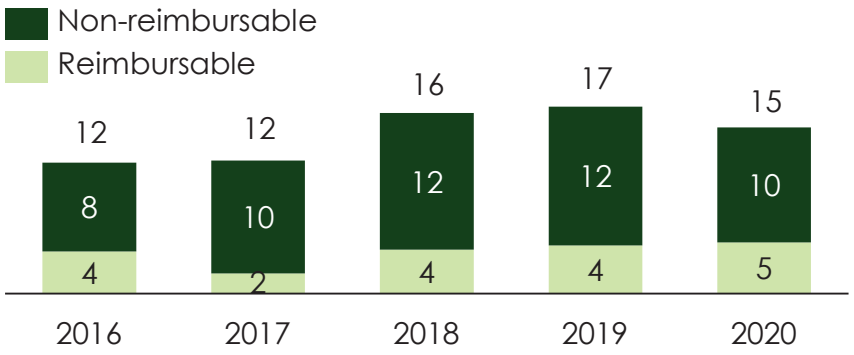
From 2016 to 2021, forgone savings in the pharmacy sector amounted to about EUR 12–17 million. Most savings come from non-reimbursable medicines.

Our estimate is based on the assumption that a PI medicine is always purchased and capable of responding to demand

We have determined the savings assuming that the most affordable PI medicine is always purchased and that the company engaged in parallel imports is able to fully meet the demand. Hence, the calculations on forgone savings represent an ideal state of affairs.

Figure 15. Forgone savings from parallel imports in the pharmacy sector during 2016–2020

EUR million



N.B.: The savings in the pharmacy sector are calculated at consumer prices. Calculations take into account lower tax revenues on value added and pharmacy taxes due to the lower prices of pharmaceuticals.

Source: Copenhagen Economics based on data provided by the Pharmaceutical Information Centre

3
SAVINGS IN THE HOSPITAL SECTOR

Competitive tendering for pharmaceuticals in the hospital sector

Unlike in the pharmacy sector, manufacturers enjoy greater freedom in the hospital sector when price-setting their products. In the hospital sector, procurement of pharmaceuticals is governed by the Act on Public Contracts.

Competitive tendering by expert responsibility areas (erva) typically organised every 1–3 years

Most pharmaceutical purchases by expert responsibility areas are put out to open tender. Tenders are typically invited every 1–3 years depending on the party organising the bidding. Aside from regional tendering, there may be nationwide tendering rounds. For example, the procurement of rare and expensive medicines is usually organised at the national level.[1]High-cost medicines are usually put out to open tender every year, basic medicines every two years and low-cost medicines every three years.[2]

Price not the only criterion in competitive tendering

In principle, it is possible that the contract is not always awarded to the cheapest medicine in competitive tendering. There are other criteria aside from price, such as drug safety or the cost arising from the substitution of the product.[1]

Since PI medicines are identical to original products, it is very rare that they would not be selected if the price is the lowest. For this report, we have been able to exclude situations in which a PI product failed to win the contract despite the lowest price.

Risk-sharing agreements affect actual price

Underlying risk-sharing agreements is the hospitals' need to manage uncertainties related to pharmaceutical expenditure and efficacy. With risk-sharing agreements, the actual price of a medicine depends on the terms of contract agreed upon between the hospital and pharmaceutical company. Under these agreements, the actual price of the product may be based on its economy or efficacy.[2] In this report, we have not been able to determine actual prices in situations involving risk-sharing agreements.

In case of delivery problems, the party winning the contract compensates for the difference in price between its product and the substitute.

Hospitals naturally purchase substitute products if the winner faces problems with deliveries. In these situations, the winning supplier is required to compensate the difference between the contract price and the price of the substitute product. In addition to compensation, suppliers are required to pay contractual penalties in connection with substitution. Total contractual penalties increase relative to increasing traded volumes.[3]

Since the price difference must be paid, we are able to determine the direct savings for the required volume in the substitution group involved. It should be noted that we are not able to distinguish between public and private sector medicine purchases in the hospital sector; see the Methodology section starting on page 27.

Winners of competitive tendering rounds are exposed to risks arising from delivery problems because they, if unable to deliver, are called upon to pay the difference in the price of their product and the substitute medicine. This risk is highlighted in parallel imports of pharmaceuticals. Parallel importers cannot always predict the volumes of pharmaceuticals they will be able to buy from other EU/EEA countries. Nor can they be sure of the prices prevailing during the tendering period.

Long contracts have mixed effects on competition

The contracts awarded in competitive tendering in the hospital sector have a duration of 1–3 years. This means that the supplier who wins the contract can be assured of steady demand for a long period of time. This may encourage prospective suppliers to set the price low. However, long-term contracts and stricter delivery obligations mean that fewer suppliers submit tenders. If a party who loses the contract withdraws from the market completely, this may limit competition in tendering.

Increasing expenditure in the hospital sector

From 2016 to 2019, total expenditure in the hospital sector increased by 42%. Over the same period, expenditure in the pharmacy sector increased by 6%; see Figure 4, page 8. It is thought to be due to new expensive medicines being placed on the market.[4] In future, this may increase the importance of parallel imports in the hospital sector.

1. Havo (2013), Sairaaloiden lääkehankinnat ja yhteistyö erityisvastuualueilla (Pharmaceuticals procurement by hospitals and cooperation within expert responsibility areas) 2. Suppliers of Parallel Imported Medicines in Finland
2. Honkanen H, Snicker K, Ahlamaa J. Lääkkeiden riskinjakosopimukset Suomen sairaaloissa – kyselytutkimus (Risk-sharing agreements on medicines in Finnish hospitals – survey (2019). Lääkärilehti 2019;49:2872-2876
3. Information on terms of contract provided by the Suppliers of Parallel Imported Medicines in Finland 4. Ministry of Social Affairs and Health (2020), Lääkehoidon kokonaiskustannukset ja apteekkitalous – esiselvitys (Pharmaceutical economy and the total cost of pharmacotherapy – Preliminary report)

Savings from the parallel import of pharmaceuticals in the hospital sector

Savings in the hospital sector total EUR 10 million

According to our calculations, the parallel import of pharmaceuticals generated savings of EUR 10 million in the hospital sector during 2016–2020.

For the calculations, we made use of the data on competitive tendering by hospitals provided by the Suppliers of Parallel Imported Medicines in Finland. The data set includes actual prices offered in competitive tendering. By matching this information with the data from the Pharmaceutical Information Centre, we are able to determine the volumes consumed in the hospital sector.

We have eliminated generic products where possible in order to only determine savings derived exclusively from parallel imports.

Indirect savings EUR 7 million

Most of the savings in the hospital sector consist of indirect savings. We have determined the indirect savings by comparing pharmaceutical expenditure at the original manufacturers' prices in the absence of competition with the expenditure that would have materialised at the original manufacturers' prices in situations in which they are faced with competition. The price without competition is the first observed price of the original manufacturer. The use of the first observed price in the saving calculations gives us conservative estimates of indirect savings because in some medicine groups, parallel imports have occurred since the early years of the period covered by the data.

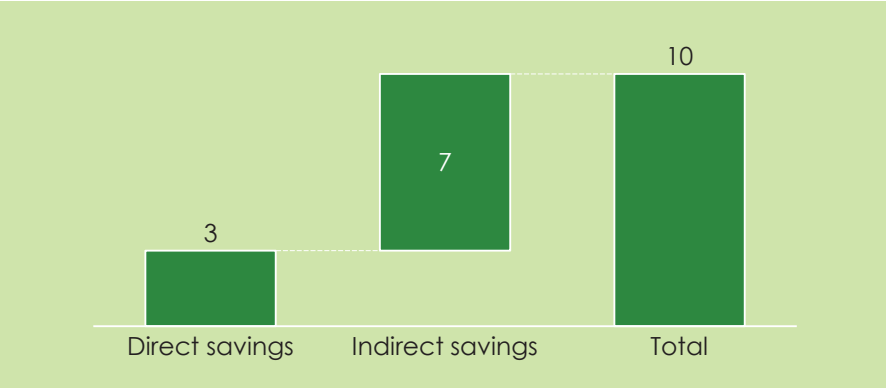
We have not determined other indirect savings for products in which parallel importers do not compete with original manufacturers even though the mere possibility of competition may, as such, reduce the prices charged by original manufacturers.

Direct savings EUR 3 million

Direct savings in the hospital sector amounted to EUR 3 million. The savings arise exclusively from the difference in price between PI products and originally produced medicines.

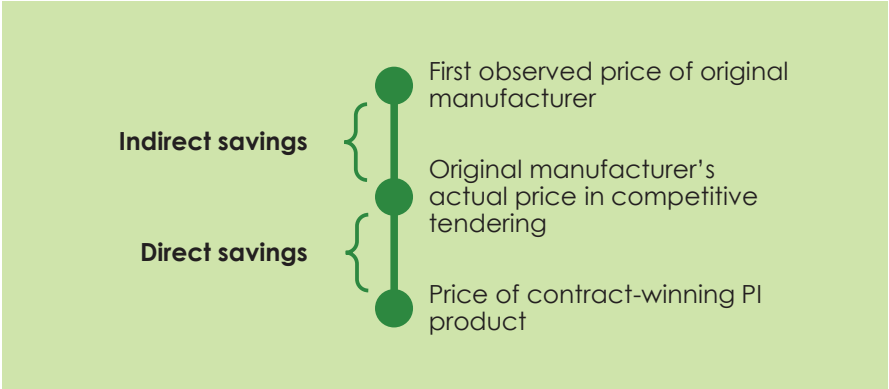
Figure 16. Saving from parallel import in the hospital sector 2016–2020

EUR million



N.B.: The savings in the hospital sector are calculated at wholesale prices.
Source: Copenhagen Economics based on hospital tendering data provided by customers

Figure 17. Prices used in the pharmacy sector calculations



Source: Copenhagen Economics

Annual savings from parallel import of pharmaceuticals in the hospital sector

A steady increase in direct savings in the hospital sector

Direct savings in the hospital sector have been increasing steadily year on year from EUR 30,000 in 2016 to EUR 800,000 in 2020.

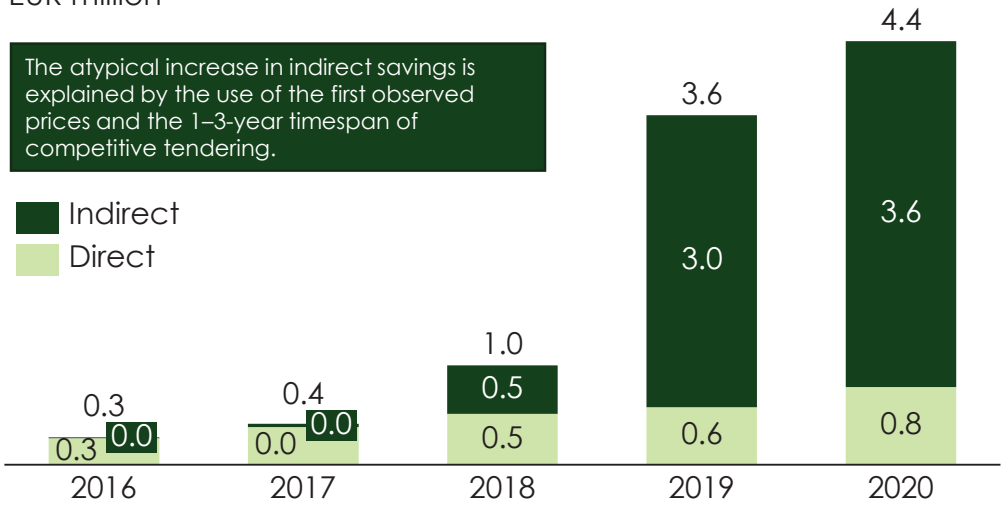
Increase in indirect savings explained by the method used

Most of the savings in the hospital sector consist of indirect savings, particularly during 2019–2020. This is partly due to the method of the study: for the original manufacturer's price, we have used the first observed price of the original product without competition. As a result, the indirect savings in the first few years are naturally low. Indirect savings increase in increments because competitive tendering for pharmaceuticals covers a period of several years. Consequently, the first observed price of an original product noted in the early years of 2016–2017 cannot fall until the following tendering period.

Since we use the first observed prices in a situation in which competition from parallel imports was present in some medicine groups, we regard the results as conservative. This is apparent in the modest initial savings in particular.

Figure 18. Direct and indirect annual savings in the hospital sector for reimbursable and non-reimbursable medicines

EUR million



N.B.: The savings in the hospital sector are calculated at wholesale prices.
Source: Copenhagen Economics based on hospital tendering data provided by customers

Conclusions

Parallel import of pharmaceuticals bring savings to Finland

We estimate that the total savings from the parallel import of pharmaceuticals during 2016–2020 amounted to EUR 41 million. Since the average market share of PI products in this period was 3%[1] we estimate the average savings from parallel imports at 8%. Most of the savings occurred in the pharmacy sector in which they totalled EUR 32 million. At the same time, the savings in the hospital sector were EUR 10 million.

Savings from the parallel import of pharmaceuticals consist of direct and indirect savings. The direct savings due to the price difference between PI and originally produced medicines were EUR 17 million. Indirect savings that arise from the difference between the price of original products with competition and the estimated price without competition were EUR 24 million. In other words, the competition created by parallel imports is assumed to reduce the prices charged by original manufactures and thereby leads to savings. Total savings benefit both patients and taxpayers. We estimate that patients saved EUR 19 million and taxpayers EUR 23 million.

In a previous report on Denmark, we calculated that the savings from the parallel import of pharmaceuticals in 2018 were in the region of DKK 610 million[2], or EUR 82 million. In this report, we have estimated the savings achieved in 2020 at EUR 16 million, one fifth of the savings made in Denmark in 2018. Considering that the market shares of PI products are much larger in Denmark, the results are consistent.

Savings from parallel import could be substantially bigger

Aside from direct and indirect savings, we also found that 'forgone savings' during 2016–2020 amounted to EUR 72 million. These savings would have materialised if patients had always bought the most affordable PI medicine instead of the original products actually sold. The results suggest that there is ample room for further savings from parallel imports. The amount of savings potentially available can be affected through regulatory amendments.

Potential barriers to the increase of the market share of parallel imports

Medicine substitution and the reference price system do not guarantee that the cheapest medicine is selected. A report by the Finnish Competition and Consumer Authority on the pharmacy market highlighted, *inter alia*, the problem that the incentives available to pharmacies do not encourage them to offer the least expensive substitutable product. At present, because of the medicine tariff system, pharmacies earn a higher absolute margin on more expensive pharmaceuticals. The absence of financial incentives for substitution may cause problems in the operation of the law.[3]

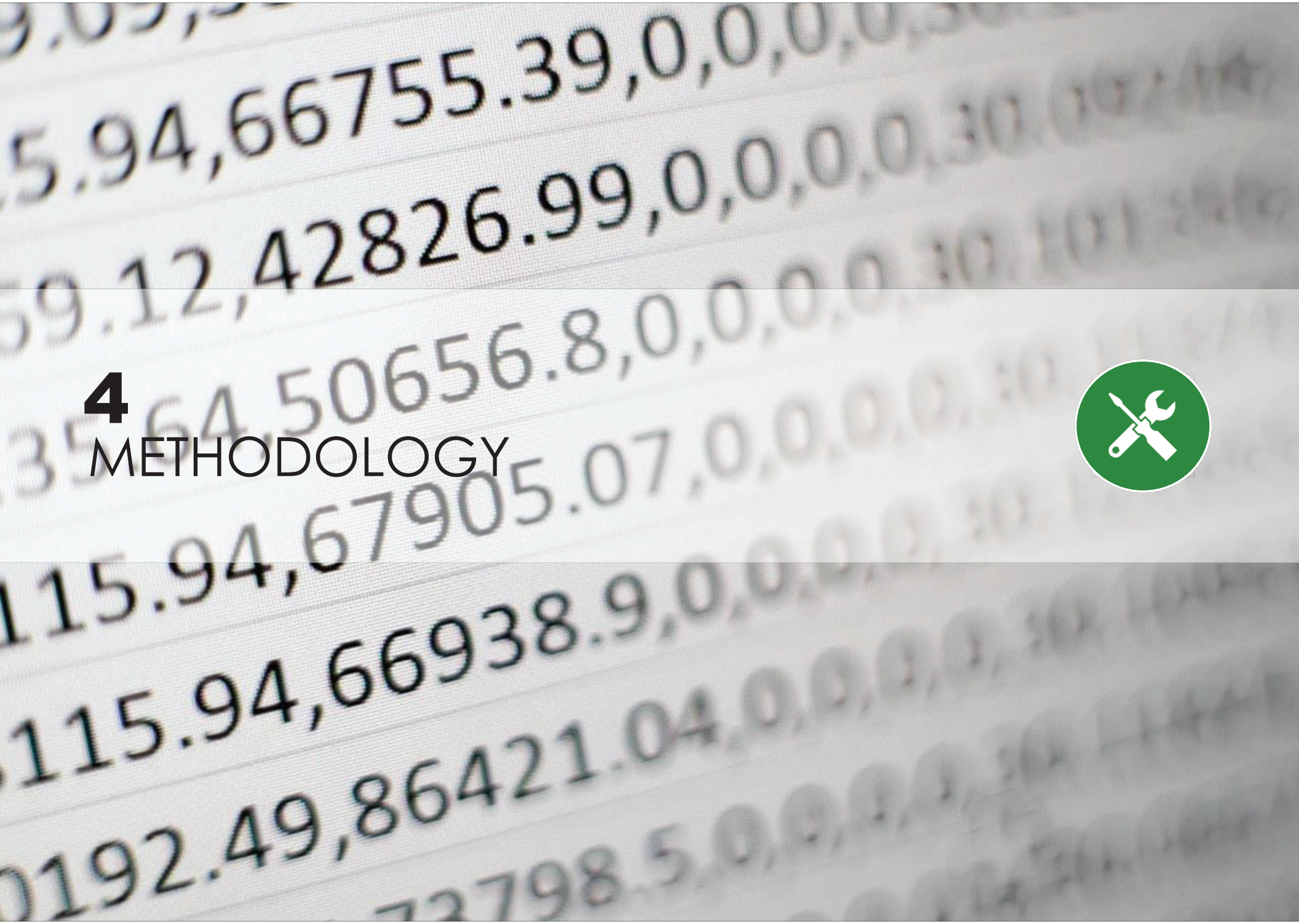
Although the market share of parallel imports is bigger in the hospital sector, and hospitals always put pharmaceutical purchases out to open tender, parallel imports in the hospital sector may be hampered by substantial contractual penalties applied in competitive tendering in situations where the hospital is compelled to swap medicines. As already mentioned, the parallel import of pharmaceuticals is an uncertain business because companies are dependent on the output and prices of original manufacturers. This creates risks and constitutes a barrier for parallel importers to participate in competitive tendering.

Our findings are consistent with the view that the reform to the reference price system has increased savings from parallel imports

The reference price system may contribute to savings in two ways. First, the inclusion of PI pharmaceuticals in the reference price system together with just original products gave customers a financial incentive to substitute medicines. Second, the legal amendment improved the efficiency of substitution, thereby creating more favourable conditions for competition. Abacus and 2Care4 entered the Finnish market after the reform to the reference price system.

A follow-up project could take a closer look at the potential savings offered by parallel imports. For example, measures to improve the competitive environment for parallel importers and related impacts could benefit from further study.

1. The market shares are 2016–2020 averages based on the Pharmarket data from the Pharmaceutical Information Centre. The market shares in 2020 were 2.9% in the pharmacy sector and 6.4% in the hospital sector.
2. Copenhagen Economics, (2019), The economic impact of parallel imports of pharmaceuticals: an assessment of savings in Denmark: https://www.copenhageneconomics.com/the-economic-impact-of-parallel-imports-of-pharmaceuticals.pdf
3. FCCA (2020), Apteekkimarkkinoiden kehittäminen (Development of the pharmacy market),: https://www.kkv.fi/kkv-suomi/julkaisut/selvitykset/2020/kkv-selvityksia-5-2020-apteekkimarkkinoiden-kehittaminen.pdf & Mikä lääkkeissä maksaa? (What costs in medicines?) VNTEAS (2021): https://julkaisut.valtioneuvosto.fi10024/162939/VNTEAS_2021_19.pdf



4 METHODOLOGY

Methodology

For the purpose of this analysis, we conducted a literature review and background interviews with five experts in the pharmaceuticals field; see Table 2. The interviewees were health economists and government officials working with competition and regulation in the pharmaceuticals market.

The purpose of the interviews and background studies was to ensure that the underlying assumptions used in the determination of direct, indirect and forgone savings were as accurate as possible.

Calculation of direct and indirect savings from parallel import

In this report, we determined the savings from the parallel import of medicines in Finland during 2016–2020. Total savings were calculated by adding up direct and indirect savings. Forgone savings were left out of total savings and analysed separately.

We determined direct savings by comparing actual pharmaceutical expenditure with a situation in which all PI medicines had been purchased at the price of original products.

Indirect savings were calculated by comparing pharmaceutical expenditure at the current prices of originally produced medicines with a situation in which these prices would be higher than today because PI medicines create competitive pressures on pricing.

Consumer prices in the pharmacy sector and wholesale prices in the hospital sector

Savings in the pharmacy sector were determined at consumer prices, i.e., at retail prices subject to tax. In the hospital sector, savings were determined at wholesale prices. The same approach is used by the Social Insurance Institution Kela and the Finnish Medicines Agency, Fimea, in their annual Statistics on Medicines.[1]

Table 2. Interviewees

Name	Position	Organisation
Ismo Linnosmaa	Professor	University of Eastern Finland
Tanja Saxell	Senior Researcher	VATT Institute for Economic Research
Sari Valliluoto	Senior Adviser	Competition and Consumer Authority
Markus Anttinen	Economist	Competition and Consumer Authority
Lauri Pelkonen	Director	Pharmaceuticals Pricing Board

Source: Copenhagen Economics

1. Kela - Suomen Lääketilasto (Finnish Statistics on Medicines): https://www.kela.fi/tilastojulkaisut_suomen-laaketilasto

Methodology employed in assessing savings in the pharmacy sector

Pharmaceuticals divided into substitution groups

The Finnish Medicines Agency maintains a list of substitutable medicines. The active ingredient and its amount in interchangeable medicines are identical and hence they are substitutable.[1]

The division of products into substitution groups allowed us to match originally produced medicines with PI products, which is crucial for our calculations.

Medicines fall into three reimbursement categories or are non-reimbursable

Patients receive reimbursement for medicines that are prescribed for the treatment of a medical condition and specifically confirmed as being reimbursable.[2] Since the reimbursement status of a medicinal product within a single group of substitutable medicines may vary, we calculated savings by reimbursement category and within groups of substitutable medicines. For example, the reimbursement rate may vary within a group of products if the same medicine is reimbursable when purchased in a larger package size, but regarded as a self-medication product when purchased in a smaller package size.

Pharmaceuticals price-set twice a month

Pharmaceuticals are price-set on the 1st and 15th of each month.[3] For this reason, we calculated the savings biweekly for each group of substitutable medicines by reimbursement category.

Contents of the data sets

We received the data set containing the historical prices and volumes of pharmaceuticals sold in Finland from the Pharmaceutical Information Centre. Aside from prices and volumes, the data set included historical data on substitutable medicines, reimbursement category and daily defined doses (DDD). For the calculations, we used daily defined doses (DDD). The data contained all pharmaceuticals on sale, including non-prescription and non-reimbursable products. The data covers the years from 2016 to 2020.

Data cleaning

Our results are based on data from 387 substitution groups. Since the prices are set twice a month, we processed the information accordingly.

We started processing with 1,420 substitution groups. We went through the following data cleaning steps to finally arrive at 387 substitution groups.

- We deleted substitution groups that lacked a parallel importer.
- We deleted substitution groups with more than one supplier in addition to a parallel importer.
- We deleted substitution groups that used to have more than one supplier in addition to a parallel importer (only as of 2016 because of the data).
- We deleted medicines with no daily defined dose (DDD) or in respect of which it was impossible to determine the relationship of package size to the other medicines in the group.
- We deleted substitution groups with only one parallel importer without any other suppliers.

By eliminating all groups with more than one other supplier in addition to parallel importers, we sought to clean generic medicines from the data set. However, we were not able to eliminate such groups completely. For example, this was the case when an original manufacturer had withdrawn from the market before 2016 but parallel importers had remained together with one company producing a generic product.

By seeking to exclude generic medicines from the analysis, we only wanted to include savings solely attributable to parallel imports, which tends to make the results more conservative.

1. Generic substitution section 17 (22.12.2016/1459) & Kela: https://www.kela.fi/laakkeet-laakevaihto-ja-viitehinta
2. Health Insurance Act: 21.12.2004/1224
3. Pharmaceuticals Pricing Board (Hila): https://www.hila.fi/toiminta-ja-organisaatio/usein-kysytyt-kysymykset/

Methodology employed in assessing savings in the pharmacy sector

Since we determined the savings within substitution groups with the same reimbursement rate, indirect and direct savings were calculated using weighted averages. For example, an original manufacturer may have two package sizes within one substitution group with a different price relative to the daily defined dose.

Direct and indirect savings

To determine direct savings, we compared expenditure that would have arisen if all the pharmaceuticals on the market would have been sold at the original manufacturers' prices with the actual pharmaceutical expenditure incurred with parallel imports.

In this case, the original manufacturers' price is the real price charged when parallel importers are active on the market.

$$Direct\ savings = m_{AV\ prices} - m_{actual\ prices} = (k_{AV} + k_{RT}) * h_{AV,with\ competition} - (h_{RT} * k_{RT} + h_{AV} * k_{AV})$$

Where m = expenditure, k = volume consumed, h = unit price, RT = parallel importer and AV = original manufacturer.

We determined indirect savings by comparing the original manufacturer's price in the absence of competition with its real price when faced with competition. The price difference was then multiplied by volume.

$$Indirect\ savings = (h_{AV,\ no\ competition} - h_{AV,with\ competition}) * (k_{AV} + k_{RT})$$

Forgone savings

Aside from direct and indirect savings, we estimated the forgone savings offered by parallel imports. Forgone savings mean savings that did not materialise but could have done so if the most affordable parallel-imported medicine had been purchased instead of the original product. In other words, forgone savings are unrealised savings, whereas direct and indirect savings are realised savings.

To determine forgone savings, we first calculated the difference between the original manufacturer's real price and the price of the most affordable PI medicine. Then we multiplied the price difference by the consumed volume of the originally produced medicine. Unlike in the determination of direct and indirect savings, we used the lowest observed prices for PI medicines. As a result, the forgone savings arrived at in the calculations refer to an ideal situation.

$$Forgone\ savings = (h_{AV,with\ competition} - h_{RT\ lowest\ price}) * (k_{AV})$$

When talking about forgone savings, it should be borne in mind that they refer to a situation in which the PI products can fully meet the market demand. Since parallel importers import their medicines from elsewhere in Europe, they may find it hard to respond to demand. For example, the price of a PI product in other parts of Europe may change, which impacts parallel imports.

Formation of an original manufacturer's price in the absence of competition

For the original manufacturer's price without competition, we used mostly the reasonable wholesale price set by the Pharmaceuticals Pricing Board. This was regarded as a sound approach by the interviewees. We converted the reasonable wholesale prices into consumer prices by adding to it the medicine tariff and value added tax.[1] Since the Pharmaceuticals Pricing Board only sets the reasonable wholesale price for reimbursable medicines, we were unable to apply the reasonable wholesale price to all products. For non-reimbursable medicines, we used the first observed price of the original product as the price without competition. Since the data only covers a period starting from 2016, the use of the first observed price is a conservative method because some substitution groups already included PI products in 2016.

We used consumer prices and daily defined doses

We determined savings at consumer prices converted into daily defined doses (DDD). The consumer prices were obtained directly from the data provided by the Pharmaceutical Information Centre. The reasonable wholesale price set by the Pharmaceuticals Pricing Board was converted into the consumer price through the inclusion of the medicine tariff and value added tax.[1]

1. Medicine tariff: 17.10.2013/713

Benefits of savings to taxpayers and patients

Breakdown of costs by substitution group

Kela and Fimea publish Finnish Statistics on Medicines every year. The report provides itemised lists of pharmaceutical expenditure by reimbursement category and medicine reimbursements; see Table 3. We used the report as an aid in breaking down the savings in pharmaceutical expenditure between taxpayers and patients. First, we calculated savings by reimbursement category and then allocated them to patients and taxpayers. Savings in non-reimbursable medicines were allocated directly to consumers.[1] For medicine groups falling into several categories, we used the highest reimbursement category. We did so because we were unable to accurately determine the weight of consumption between substitution groups. Moreover, some reimbursement categories are conditional in that they require a prescription. The uncertainty arising from the interpretation of these groups increased the complexity of the analysis.

Since we used the highest reimbursement category when several categories were involved, we carried out a sensitivity analysis to allocate savings to consumers and taxpayers using an overall ratio of reimbursements to pharmaceutical expenditure covering all the groups. The findings are consistent with the results broken down by medicine group.[2]

The Finnish Statistics on Medicines are only available up to 2019. For this reason, the 2020 savings were allocated on the basis of the 2019 figures.

Value added and pharmacy taxes taken into account in the calculation of savings

Naturally, tax revenues remain lower when there are parallel-imported products on the market and the expenditure on pharmaceuticals falls. Accordingly, we made allowance for lower tax revenues in our calculations.

At present, the government imposes two types of taxes on medicines bought in pharmacies. First, there is 10% value added tax on each medicine purchase. Second, there is a pharmacy tax levied on the price of medicines. The pharmacy tax is progressive and its amount is based on the size of the pharmacy. The tax is determined from turnover exclusive of VAT less the value of the contract manufacturing of medicines, sales to social and healthcare institutions and the sale of nicotine replacement products.

Additionally, the sales of products other than medicines are deducted from turnover insofar it does not exceed 20% of turnover.[3] The highest pharmacy tax rate is 11.2% when turnover, less deductions, exceeds EUR 537,406. For the purpose of this report, we used a fixed 10.45% pharmacy tax rate in assessing savings with due regard to lower tax revenues. The report on the development of the pharmaceuticals market released by the Finnish Competitive and Consumer Authority found that the median pharmacy tax rate on marginal turnover was approx. 10.45%.[4]

Table 3. Kela's reimbursement categories and Pharmaceutical expenditure

%

	Basic reimbursement (40%)	Lower special reimbursement category (65%)	Higher special reimbursement category (100%)
2016	38%	63%	97%
2017	38%	63%	97%
2018	38%	64 %	97%
2019	38%	64 %	97%
2020*	38%	64 %	97%

**We used the 2019 data in the absence of data for 2020*
Source: Kela & Fimea: Finnish Statistics on Medicines 2016–2019

1. Kela - Suomen Lääketilasto (Finnish Medicine Statistics): https://www.kela.fi/tilastojulkaisut_suomen-laaketilasto Average ratio of reimbursements to pharmaceutical expenditure varies within the range of 72–74% Using this method, we arrived at EUR 19 million in savings to patients and EUR 13 million in savings to taxpayers with the results rounded to the nearest million. 3. Tax Administration, Pharmacy tax: https://www.vero.fi/syventavat-vero-ohjeet/ohje-hakusivu/48607/apteekkiver/
4. FCCA (2020), Apteekkimarkkinoiden kehittäminen (Development of the pharmacy market), s. 20: https://www.kkv.fi/globalassets/kkv-suomi/julkaisut/selvitykset/2020/kkv-selvityksia-5-2020-apteekkimarkkinoiden-kehittaminen.pdf

Methodology in assessing savings in the hospital sector

Unlike pharmacies, hospitals purchase products at a single price quoted in the winning tender.

Direct savings

To determine savings from parallel import of pharmaceuticals in the hospital sector, we compared the total expenditure that would have been incurred if all the medicines had been sold at the original manufacturers' prices with the actual expenditure incurred when PI products are available.

$$Direct\ savings = m_{AV\ prices} - m_{actual\ prices} = (k_{AV} + k_{RT}) * h_{AV,with\ competition} - h_{RT} * (k_{AV} + k_{RT})$$

Where m = expenditure, k = volume consumed, h = unit price, RT = parallel importer and AV = original manufacturer.

Indirect savings

To determine indirect savings, we compared expenditure that would have been incurred if the same volume of medicines had been sold at the original manufacturers' prices without competition with expenditure that would have been incurred if the same volume of medicines had been sold at the actual original manufacturers' prices with competition.

$$\text{Indirect savings} = (h_{AV,\ monopoly} - h_{AV,with\ competition}) * (m_{AV} + m_{RT})$$

Competitive tendering for pharmaceuticals in the hospital sector

Normally, tenders for hospital medicines are invited every 1 to 3 years. Tendering is based on the ATC-5 classification with dose forms and strengths put out to open tender separately. Competitive tendering is organised on a regional basis. Finland is divided into 20 hospital districts, each of which belongs to one of the five expert responsibility areas. Most hospital districts engage in cooperation within expert responsibility areas with a central hospital pharmacy handling competitive tendering for all the pharmaceuticals needed in the expert responsibility area. Exceptionally, competitive tendering for some products, such as HIV medicines, may be organised jointly by several expert responsibility areas.

Contents of the data sets

For this report, Abacus, Orifarm and Paranova, three parallel importers, provided us with the results of the competitive tendering rounds in which they had participated. The data also included the tenders submitted by 2Care4, another parallel importer, provided that the company had participated in a round of competitive tendering organised by the same contracting entity as another parallel importer in Finland. The data provided in PDF format was converted into a readable format using Python programming language. We were able to glean the prices of pharmaceutical from this data.

Additionally, we had sales data from the Pharmaceutical Information Centre at our disposal. The data provides sales figures issued every two weeks, broken down by hospital district.

We matched the prices from the tenders with the volumes reported by the Pharmaceutical Information Centre based on the VNR number, district and the tendering period.

Data cleaning

We carried out the following data cleaning steps to create the final data set.

- We deleted groups of medicines for which there were no parallel importers.
- We deleted groups of medicines for which there was more than one supplier in addition to parallel importers.
- Finally, we deleted the groups of medicines included in regional tendering in which the prices were withheld (N=14).

Please note

Because of the limitations of the data, we were unable to determine savings in the hospital sector accurately.

- The data provided by the Pharmaceutical Information Centre also includes medicine sales to private hospitals. As we were unable to exclude these volumes from the calculations on the hospital sector, this may slightly exaggerate the estimated savings.
- We were unable to purge risk-sharing agreements from the data, and therefore some of the actual pharmaceutical prices may differ from what the tendering data implies.

Price elasticity of demand and original manufacturers' incentives for product development

This report provides calculations on savings from parallel import of pharmaceuticals during 2016–2020. For the purposes of the report, we assumed that demand for pharmaceuticals is inelastic and that the effect of parallel imports on original manufacturers' product development efforts was negligible.

Inelastic demand

To determine direct and indirect savings, we compared two situations: without parallel imports and with parallel imports. Consumption was assumed to be the same in both cases. This means that we assume that demand for pharmaceuticals is inelastic. In other words, we assume that price levels do not affect the consumption of medicines.

Normally, when the price of a product increases, demand falls. We assume that this is not the case with pharmaceuticals because a large percentage of the medicines are prescribed by doctors and a large percentage of them are reimbursable to patients. We are aware that some of the medicines dispensed by pharmacies are not reimbursable and that patients pay the full price for them. In this sense, there is a degree of price elasticity in demand. It was pointed out in the background interviews that price elasticity could be applied in the calculations, but a completely inelastic demand was not perceived as a problem considering the premises on which the study was based. As an alternative to inelastic demand, we could have looked for price elasticities in academic literature, but then there would have been problems with the selection and application of the correct elasticity, because they may exhibit differences depending on the group involved.

If price elasticity had been used, the direct savings would also have been lower, but in that case there would also have been patients who would have been unable to receive all the medicines they needed. For this reason, it is extremely complicated to determine actual savings from parallel imports of pharmaceuticals if price elasticity is factored in.

Original manufacturers' incentives for product development

Parallel imports of pharmaceuticals limit the original manufacturers' freedom to charge higher prices for products in countries in which the general price level is high. As a result, parallel imports may eat into the profits of original manufacturers.

When profits fall as a result of parallel imports, original manufacturers may respond by starting to behave differently. Parallel imports may affect original manufactures in two ways. First, parallel imports may erode original manufacturers' incentives for investing in product development if parallel imports have a substantial impact on the profits earned on new medicines. Second, parallel imports may cause original manufacturers to rethink the launching and price-setting of medicines in the EU/EEA countries from which they are imported into Finland.

For instance, original manufacturers may increase the price in the countries from which medicines are parallel-imported or postpone the launching of medicines in such countries.

Finland accounts for an very small percentage of the world's pharmaceutical market and parallel imports. It would appear that the revenue generated in Finland has little impact on the total earnings of original manufacturers. The experts interviewed for this report were of the same opinion.

If this study were to be conducted across Europe or globally, it would have to assess original manufacturers' incentives for product development and their impact on total savings in order to provide reliable results.

Savings from parallel import of pharmaceuticals in Finland

2016–2020

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Copenhagen Economics is one of the leading economic consultancies in Europe. Founded in 2000, we currently employ more than 90 people operating from our offices in Copenhagen, Stockholm, Helsinki and Brussels. Global Competition Review (GCR) lists Copenhagen Economics among the Top-20 economic consultancies in the world and has done so since 2006.

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