Copenhagen Economics

THE ECONOMIC IMPACT OF PARALLEL IMPORTS OF PHARMACEUTICALS

An assessment of savings in Denmark in 2021

The Danish Association of Parallel Importers of Pharmaceuticals

June 2022

Preface

The Danish Association of Parallel Importers of Pharmaceuticals (Foreningen for Parallelimportører af Medicin) has asked Copenhagen Economics to quantify the savings that parallel imports of pharmaceuticals gave rise to in Denmark in 2021. The assessment concerns primary-sector pharmaceuticals dispensed at pharmacies and hospital sector pharmaceuticals.

To enable us to carry out the analysis of the primary care sector, we received data on traded volumes from the parallel importer Orifarm, and data on the prices of primary-sector pharmaceuticals since 2008 from Danish Pharmaceutical Information (Dansk Lægemiddel Information). As regards the savings in the hospital sector, we have based our calculations on confidential data on traded volumes and prices from 2care4, Abacus Medicine, Orifarm, and Paranova. In addition, we have been in dialogue with public authorities in the area.

We would like to thank the Danish Association of Parallel Importers of Pharmaceuticals, 2care4, Abacus Medicine, and Orifarm for providing the data that formed the basis of the project and the calculations.

Copenhagen Economics is responsible for the analyses in the report, including the calculations, data processing, interpretations, and conclusions. The conclusions are exclusively those of Copenhagen Economics and do not necessarily reflect the opinions of the project's sources or partners.

Contributors to the analysis

Copenhagen Economics CE

The analysis was conducted by Copenhagen Economics.

2care4 ABACUS MEDICINE ORIFARM DLi

The analysis is primarily based on data from Danish Pharmaceutical Information and the parallel importers 2care4, Abacus Medicine, and Orifarm.

FPM

The analysis was commissioned by the Danish Association of Parallel Importers of Pharmaceuticals.

Executive summary

Parallel imports of pharmaceuticals has taken place in Denmark and the rest of the EU since the 1970s. In 2021, parallel imports accounted for 16% of turnover in the Danish market for medicinal products. In 2018, the share was 14%. Parallel-imported pharmaceuticals are original pharmaceuticals imported from another EU/EEA country where they are cheaper than in Denmark. Hence, they are the same products as those sold by original manufacturers in Denmark.

According to our calculations, the total savings from parallel imports of pharmaceuticals in 2021 amounted to DKK 740 million, or 3% of the total cost of pharmaceuticals in Denmark.

The analyses in this report are based on 2021 data on volumes, prices and costs of medicines in the primary sector, i.e. medicines dispensed in pharmacies, and in the hospital sector.

Parallel imports of pharmaceuticals resulted in savings of DKK 740 million in 2021

Our analysis suggests that the total savings from parallel imports of pharmaceuticals in 2021 amounted to DKK 740 million, calculated on the basis of the pharmacies' purchase prices (PPP); see Figure 1. This corresponds to 3% of the total cost of pharmaceuticals in Denmark, or an average saving on parallel-imported products of 16%.

Most savings occurred in the primary care sector, where they amounted to DKK 627 million, and where the parallel importers had a market share of 30%. In the hospital sector, where the parallel importers' market share was 8%, the corresponding savings amounted to DKK 113 million.

Parallel imports of pharmaceuticals leads to direct and indirect savings. The direct savings amounted to DKK 399 million, which reflects the price difference between the cheapest parallel importers and the original manufacturers. The indirect savings are estimated and amount to DKK 341 million, which reflects the difference between the original manufacturers' estimated monopoly prices and their prices when faced with competition from parallel importers. In other words, the presence of parallel importers incites lower prices among the original manufacturers.

Savings have increased by 21% since 2018

In 2018, we carried out a similar analysis of the impact of parallel-imported pharmaceuticals, which suggested total savings of DKK 610 million. This means that over the course of three years, the savings have increased by DKK 130 million, corresponding to 21%. This increase in total savings is mainly driven by the fact that parallel importers have gained greater market shares during the period.

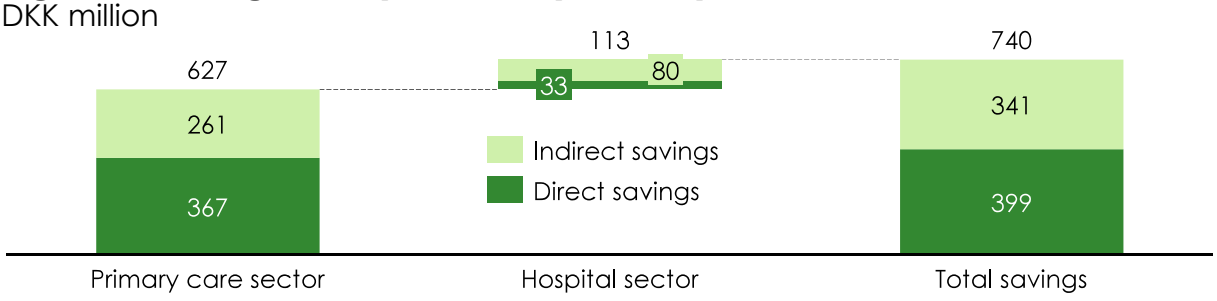
The amount saved depends on the conditions for parallel imports

The relatively large savings in the primary care sector of DKK 627 million in 2021 are partly due to the more supportive regulatory environment in this sector compared to the hospital sector. In 2018, the savings in the primary care sector amounted to DKK 545 million.

In the hospital sector, the savings in 2021 amounted to DKK 113 million, which corresponds to a large increase of 74% since 2018, when the savings were DKK 65 million. The large increase has coincided with the fact that the regulations in the hospital sector have made the market slightly more attractive to parallel importers.

The development since 2018 suggests that an even more favourable regulatory environment can lead to even greater savings, but also that the existing savings can only be realised as long as the regulatory environment enables and supports parallel imports of medicines.

Figure 1. Savings from parallel imports of pharmaceuticals in 2021



Note: All prices and savings are calculated on the basis of the PPP (pharmacy purchase price)
Sources: Copenhagen Economics, based on Danish Pharmaceutical Information, Amgros and the Danish Association of Parallel Importers of Pharmaceuticals and members

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PARALLEL IMPORTS OF PHARMACEUTICALS IN DENMARK

What is parallel imports of pharmaceuticals?

Parallel-imported pharmaceuticals are original medicinal products imported from an EU/EEA country[1] where they are cheaper than in Denmark. They are the same products as those sold by original manufacturers in Denmark. All parallel-imported pharmaceuticals are controlled by the Danish Medicines Agency and sold to pharmacies and hospitals exclusively through approved pharmaceutical wholesalers.[2]

Figure 2 below shows the costs of pharmaceuticals in the primary care and hospital sectors in Denmark in 2018 and 2021, as well as the volume of parallel imports. In both sectors, the costs of both the originally produced and parallel-imported pharmaceuticals increased over the period, although the overall increase in the primary care sector was limited.

Parallel imports of pharmaceuticals has taken place in Denmark and the rest of the EU since the 1970s,[3] and today it makes up a significant share of the market for primary sector pharmaceuticals in Denmark and elsewhere. Figure 3 shows the parallel importers' market shares in a number of European countries in 2016. Denmark stands out because the share of parallel-imported pharmaceuticals in the primary care sector was more than four times larger than the average of the other countries in the sample.

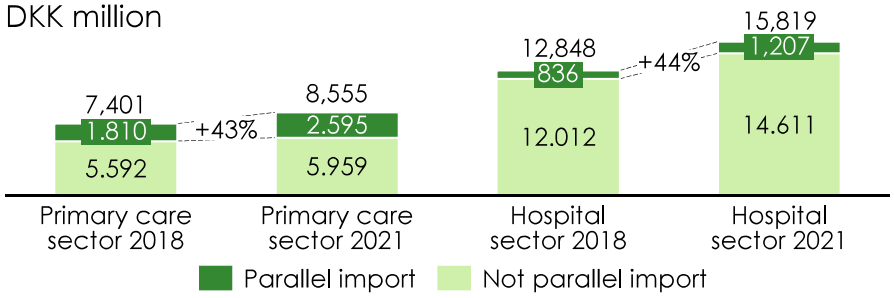
Parallel imports is made possible by the fact that the prices of pharmaceuticals vary among the EU/EEA countries. This variation is due partly to differences in national regulations and partly to the fact that the original manufacturers price their products higher in some countries than in others.

The price differences allow parallel importers to buy pharmaceuticals in a country where the prices are relatively low in order to resell them at a profit in countries where prices are higher. If multiple parallel importers are supplying the same pharmaceuticals in a country, they will be in competition with each other, which further contributes to reducing prices.

Parallel imports usually take place in the market for original pharmaceuticals and before the expiry of patents, when there is no competition from generic products. Parallel-imported pharmaceuticals should not be confused with generic or biosimilar pharmaceuticals, which broadly speaking are copies of the original products, and are not necessarily parallel-imported.

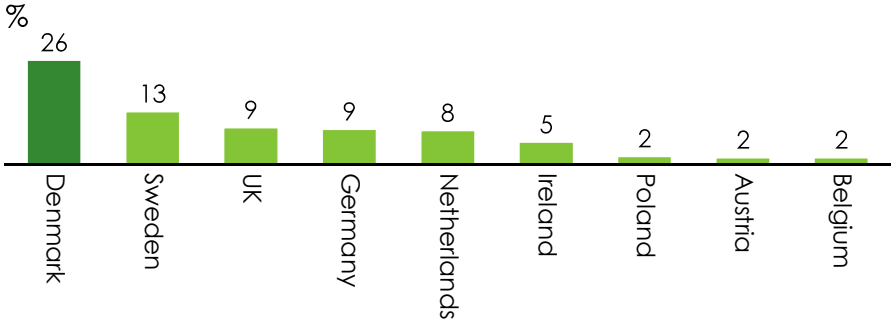
An exhaustive definition and introduction to parallel imports of pharmaceuticals can be found on the website Retsinformation.dk under 'Guidelines on parallel imports of pharmaceuticals'.[4]

Figure 2. Turnover in the Danish primary care and hospital sectors in Denmark in 2018 and 2021



Note: All prices and savings are calculated on the basis of the savings on PPP (pharmacy purchase price)
Source: Danish Pharmaceutical Information

Figure 3. Parallel importers' market share in the primary care sectors of a sample of countries, 2016



Source: EFPIA; see efpia.eu/publications/data-center/the-pharma-industry-in-figures-economy/parallel-imports

1 List of countries in the EU and EEA (European Economic Area), the Danish Ministry of Taxation; see skat.dk/skat.aspx?oid=2244499
2 The Danish Association of Parallel Importers of Pharmaceuticals; see fpm.dk/parallelimport/hvad-er-parallelimport
3 Ulrika Enemark (2006), The economic impact of parallel import of pharmaceuticals
4 Retsinformation – Guideline no. 9170 of 27 February 2018; see retsinformation.dk/Forms/R0710.aspx?id=198382

The value chain for parallel imports of pharmaceuticals in Denmark

When primary-sector pharmaceuticals are dispensed to patients at pharmacies, they come from either an original manufacturer or a parallel importer. Parallel imports occur when the pharmacies in Denmark can buy a parallel-imported product at a cheaper price than the price of a corresponding product from the original manufacturer.

In the example in Figure 4 on the right, this means that patients will receive parallel-imported pharmaceuticals when:

The price charged by the original manufacturer to a wholesaler in the Netherlands
+ the Dutch wholesaler's profit
+ the parallel importer's profit

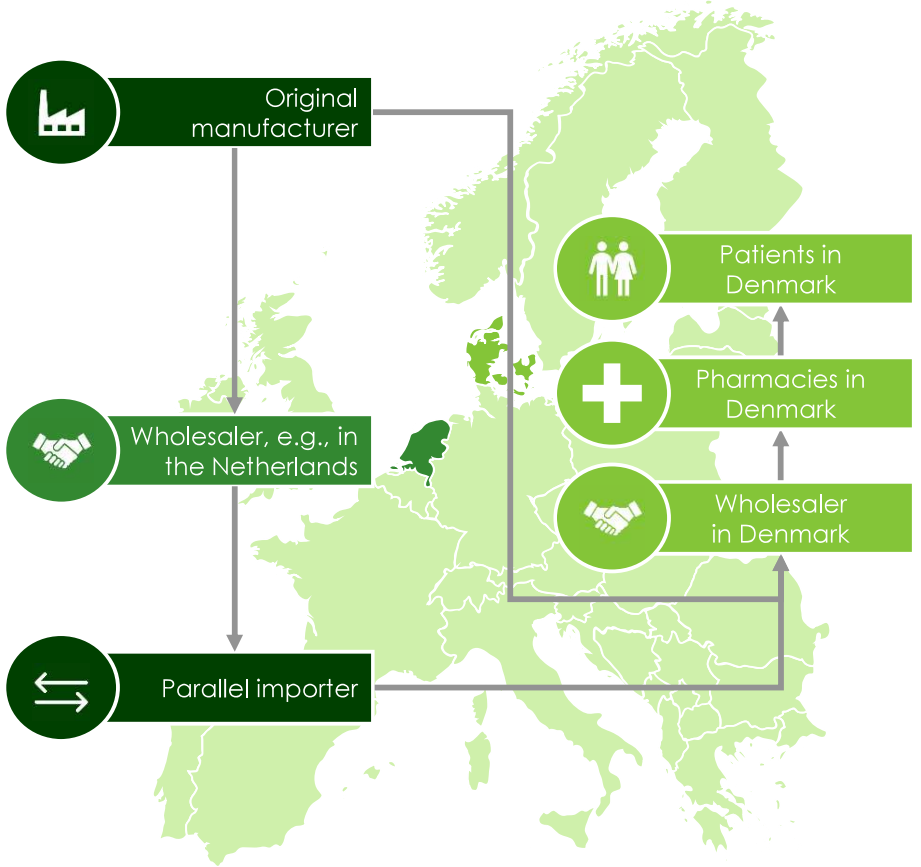
is lower than:

The price charged by the original manufacturer to a wholesaler in Denmark

In this example, the parallel importer purchases its products from a wholesaler situated in the Netherlands. In practice, parallel importers source their products throughout the EU/EEA area, partly depending on where prices are lowest and where the products are available in sufficiently large volumes.

The value chain in the hospital sector is in principle similar to that of the primary care sector but differs in that it includes hospital pharmacies and Amgros instead of pharmacies and wholesalers in Denmark.[1]

Figure 4. The path to market for originally produced and parallel-imported primary sector pharmaceuticals in Denmark



Note: The figure is illustrative, using the Netherlands as an example, and does not show a specific product's value chain.
Source: Copenhagen Economics, based on Rikke Krause Olsen (2011), Pharmaceutical Parallel Trade: An Empirical Study of Danish Parallel Distributors' Competitive Behavior

1 Amgros (2014) Amgros udbud og effekt; see auh.dk/siteassets/afdelinger/klinisk-farmakologisk-afdeling/pdf-filer/rebild_2014-01-22/2014-01-22_flemmingsonne.pdf

Direct and indirect savings through parallel imports of pharmaceuticals

When speaking of parallel imports of pharmaceuticals, we distinguish between two types of savings: *direct savings* and *indirect savings*.

The principles of direct, indirect and overall savings from parallel imports of pharmaceuticals are illustrated in Figure 5.

Primary care sector

We calculate the direct savings on a product in the primary care sector using the price difference between a parallel importer's winning price, for which the product has been sold, and the higher bid of the original manufacturer in the same tender, which has not generated revenue. We then aggregate the savings across all products in the volumes that were sold by parallel importers in 2021.

The indirect savings on a product in the primary care sector is the reduction in the original manufacturer's price in response to competition from parallel importers. To calculate the indirect savings, we use a dataset from Danish Pharmaceutical Information[1] with the original manufacturers' prices listed in tenders since 2008. Based on the dataset, we compare the original manufacturers' prices in 2021 with their average price in the year leading up to when the first parallel importer took part in a tender.[2] To calculate the indirect savings, we multiply the price difference by the volume sold. The indirect savings are as real as the direct savings, but their size is subject to greater uncertainty, since the monopoly prices cannot be observed, but must be estimated.

Hospital sector

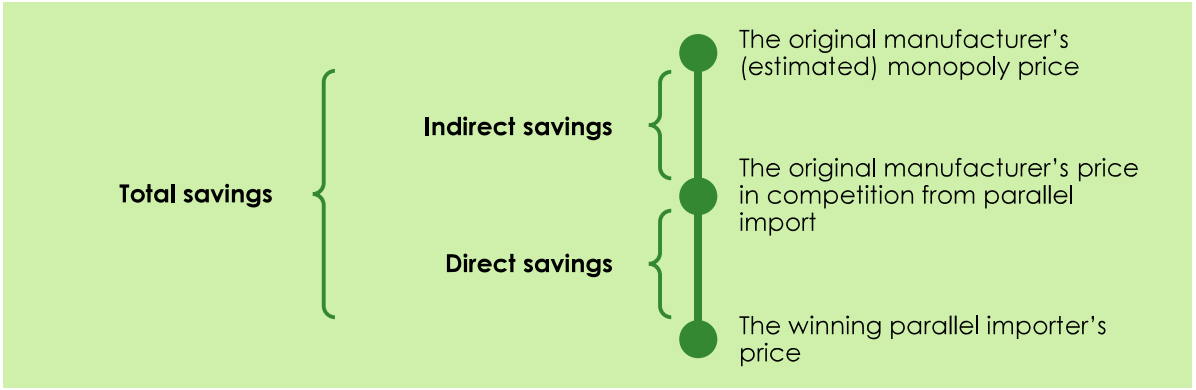
We calculate the overall savings in the hospital sector by comparing the parallel importers' sold volumes and prices with the original manufacturers' list prices, minus a discount of 14.6%[3], which Amgros on average obtained for hospital-only monopoly products in 2018. We estimate the original manufacturers' prices, since they are confidential, and we do not have direct access to them.

We separate the direct savings by comparing the savings on parallel imports with the original manufacturers' list prices with a discount of 21.6%, which Amgros on average obtained for hospital-only products with limited competition in 2018. We interpret the remaining part of the overall savings as indirect savings.

An example of the above is a product that the original manufacturer offers at a list price of DKK 100. If there is no competition, Amgros will get an average discount of 14.6% and pay DKK 85.40 for the product. If there is competition, Amgros will get an average discount of 21.6% and pay DKK 78.40 for the product. If the price of a corresponding parallel-imported product is DKK 76, which corresponds to a saving of 24% compared to the original manufacturer's list price, the direct saving is DKK 2.40. This is the difference between the parallel importer's price and the original manufacturer's price in competitive conditions. The indirect saving is DKK 7, which is the difference between the original manufacturer's price with and without competition.

We have had access to four parallel importers' prices, which together account for almost the entire turnover in the market for parallel import of pharmaceuticals in Denmark.

Figure 5. Direct, indirect and overall savings from parallel imports



Source: Copenhagen Economics

1 Danish Pharmaceutical Information A/S, dli.dk

2 In the primary care sector, there is an auction system with two-week price periods. As a general rule, the pharmacies must offer the cheapest product in a given substitution group (group of medicines with the same active ingredients); see Danish Competition and Consumer Authority (2016), Konkurrence om distribution af medicin

3 Amgros (2019), Markedet og årsslides

Competition between parallel importers contributes to lower prices

On average, parallel imports of pharmaceuticals in Denmark results in savings of 16%. These savings can be attributed to the presence of several parallel importers, which generates competition and drives prices further below the original manufacturers'.

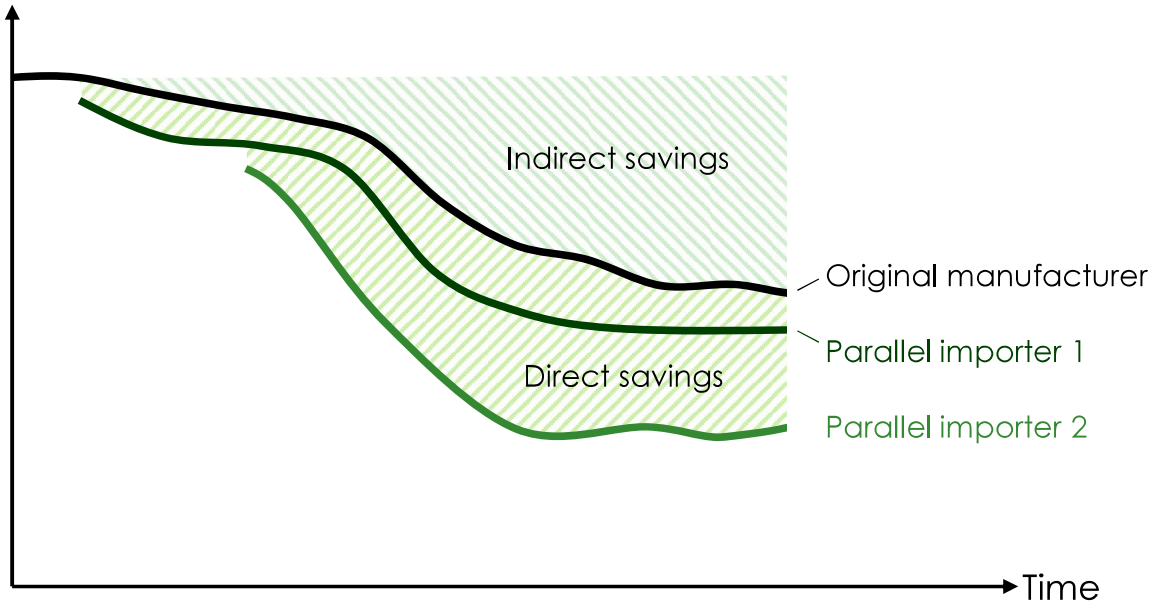
The 16% saving obtained through parallel imports reflects an average saving in the primary care and hospital sectors of 19% and 9%, respectively, compared to the prices the original manufacturers would have sold their products for in the absence of competition from the parallel importers.

If a parallel importer is alone in a market with an original manufacturer, the parallel importer will in principle have an interest in setting its price just below that of the original manufacturer. In order to do that, however, the parallel importer needs to have precise and correct information about the original manufacturer's prices prior to the tender. If the parallel importer has this information, it will win the tender and earn as much money as possible. In practice, however, there is an incentive in the primary care sector to ensure a price difference on pharmaceuticals of at least DKK 20 with a view to ensuring a high market share,[1] which gives parallel importers an incentive to undercut the original manufacturer by a certain margin.

Previous studies have found empirical evidence showing that savings obtained through parallel imports of pharmaceuticals require competition between parallel importers.[2]

In Denmark, four parallel importers cover virtually the entire market for parallel-imported pharmaceuticals. The presence of four large parallel importers implies that they compete with each other in many tenders. This competition further implies that the individual parallel importers have an incentive to set their prices marginally below those of the other parallel importers to win tenders, and this price can be significantly lower than the original manufacturer's price; see Figure 6.

Figure 6. Illustration of savings from parallel imports of pharmaceuticals



Note: The figure is illustrative and does not show savings from a specific product.
Source: Copenhagen Economics

1 The Danish Medicines Agency (2018), Substitution; see https://laegemiddelstyrelsen.dk/en/pharmacies/substitution
2 Oxera (2008), Shades of grey: arguments for and against parallel trade in pharmaceuticals

Results of previous analyses of savings from parallel imports in the primary care sector

The savings achieved through parallel imports of pharmaceuticals in Denmark have previously been analysed. The analyses carried out before those of Copenhagen Economics have focused exclusively on savings in the primary care sector, since this is where the biggest savings are found. The previous analyses found savings in the range of DKK 22-396 million per year; cf. Figure 7.

The differences between this and the previous analyses are mainly attributable to the different times at which the analyses were carried out, as well as to variations in the methods.

P. Kanavos (2004) especially stands out by using a special method which results in relatively low savings compared with the other analyses. For example, the savings in Denmark are based on just 14 products, and for most of the products the parallel importers had market shares of less than 20%. In this way, the relatively small savings follow from the methodology. A few years after the publication of this analysis, U. Enemark (2006) reviewed and rejected the methodology employed by P. Kanavos, and none of the two later analyses employed it either. Due to the above considerations, neither do we.

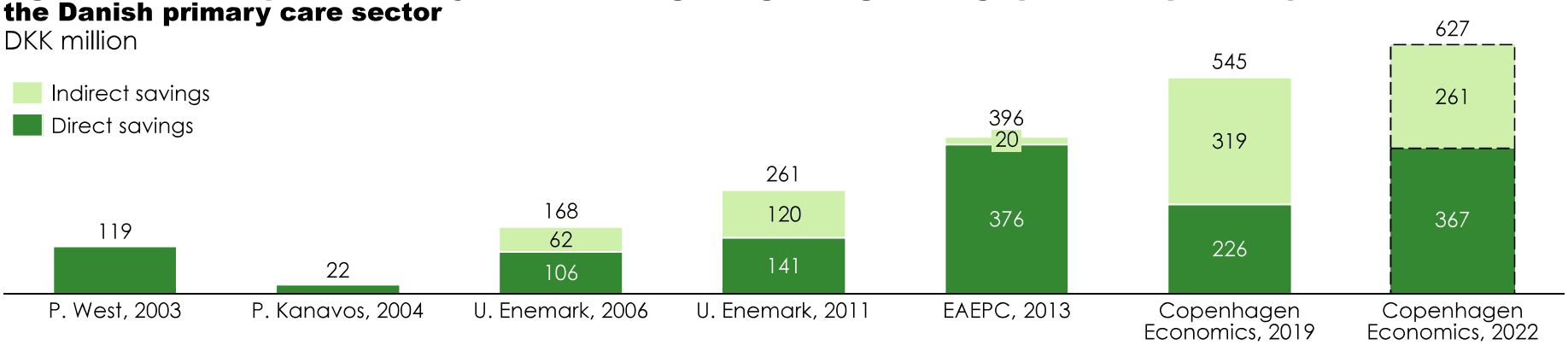
The methodology employed in Copenhagen Economics' analyses differs from the previous ones by not being based on a sample, but on the entire market for parallel imports, which improves the accuracy of the results.

The more recent analyses cover both direct and indirect savings, while the first two analyses only covered direct savings.

Given the differences between the analyses, it is uncertain to what extent the results can be compared with each other and with the results of the present analysis. If we nevertheless make a comparison, there appears to be a trend in the sense that the savings from parallel imports in the primary care sector have increased over time. It is not clear what drives this trend, but possible explanations may include increased competition between parallel importers and increasing market shares for parallel-imported pharmaceuticals.

Figure 7. This and previous analyses' results regarding savings through parallel imports of pharmaceuticals in the Danish primary care sector

DKK million



Note: All prices are specified as in the sources and have not been adjusted for price developments. We have converted from EUR to DKK based on an exchange rate of 7.466.
Sources: Peter West (2003), Benefits to Payers and Patients from Parallel Trade; Panos Kanavos (2004), The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States; Ulrika Enemark (2006), The economic impact of parallel import of pharmaceuticals; Ulrika Enemark (2011), Parallel imports of pharmaceuticals in Denmark, Germany, Sweden and the UK 2004-2009; EAEPC (2013), The Parallel Distribution Industry: A closer look at savings

The total savings increased by DKK 130 million between 2018 and 2021

Savings from parallel imports of pharmaceuticals have increased since 2018

The total savings from parallel import of pharmaceuticals have increased by DKK 130 million between 2018 and 2021; see Figure 8 below. This corresponds to an overall increase of 21%, or an average annual increase just short of 7%.[1]

The increase is mainly driven by the primary care sector

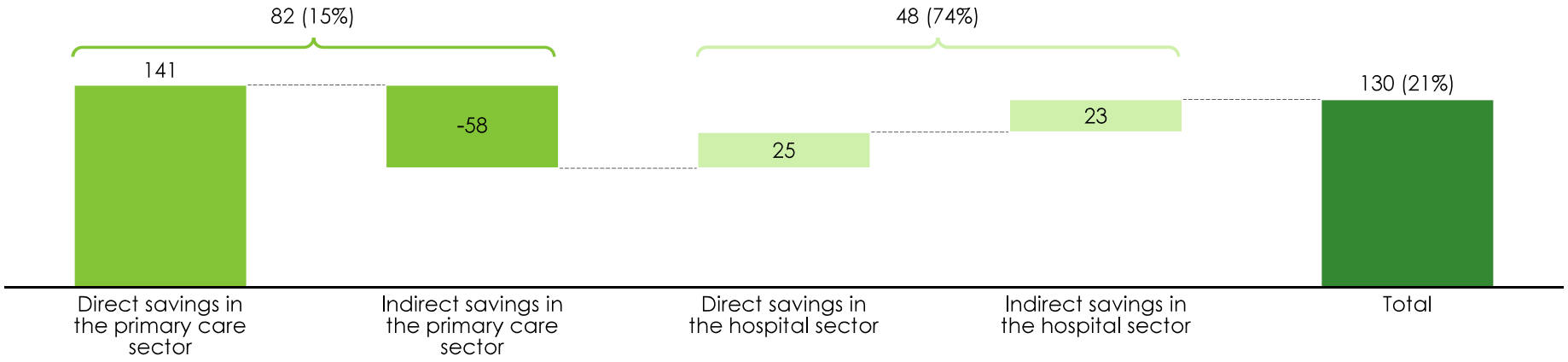
In the primary care sector, savings have increased by DKK 82 million between 2018 and 2021, a 15% increase. The increase in direct savings is mainly driven by a higher turnover among the parallel importers, whose market share increased from 26% in 2018 to 30% in 2021.

Indirect savings in the primary sector have decreased, but this is more than offset by an increase in direct savings. There are several possible explanations for the results in the primary care sector. One possibility is that there has been a shift from indirect to direct savings if original manufacturers have reduced their prices less in recent years than in the past when faced with competition from parallel importers. This would not affect the total savings in the primary sector, but give rise to the shift from indirect to direct savings.

Savings have also increased in the hospital sector

In the hospital sector, savings have increased by DKK 48 million between 2018 and 2021, corresponding to 74%. This increase is driven both by a higher turnover among the parallel importers and by a larger relative discount on average products. The parallel importers' market share has increased by one percentage point to 8% over the period. This should be seen in light of the fact that the overall market for hospital medicine has increased substantially during the period.

Figure 8. Development of savings from parallel imports of pharmaceuticals between 2018 and 2021
DKK million (%)



Note: All prices and savings are calculated on the basis of the PPP (pharmacy purchase price). Results are rounded to the nearest whole million DKK.
Sources: Copenhagen Economics, based on figures from Danish Pharmaceutical Information, Amgros and the Danish Association of Parallel Importers of Pharmaceuticals and members

1 Note that we compare results over time based on two different methodologies employed to estimate indirect savings in the primary sector. The change of methodology between this analysis and the previous one based on data from 2018 has a relatively small effect on the size of the result.

Overall savings from parallel imports of DKK 740 million in 2021

We find that the total savings resulting from parallel imports of pharmaceuticals in 2021 amounted to DKK 740 million; cf. Table 1. The largest part of the savings – DKK 627 million – occurred in the primary care sector, on medicine dispensed in pharmacies. The remaining savings of DKK 113 million occurred in the hospital sector.

The total savings of DKK 740 million correspond to 3% of the total cost of pharmaceuticals in Denmark, which is DKK 24.4 billion. The savings occur because parallel-imported pharmaceuticals on average are 16% cheaper than the same medicine would have been sold for by the original manufacturers if there had been no competition from parallel importers.

The parallel importers' overall market share of pharmaceuticals in Denmark is 16%, which reflects a relatively high market share in the primary care sector of 30% and a lower market share of 9% in the hospital sector.

The savings made through parallel imports of pharmaceuticals in the hospital sector accrue to the public healthcare sector, while the savings in the primary care sector accrue to both the public healthcare sector and the Danish patients due to co-payments amounting to around 30% of the costs.[1]

This means that all Danish taxpayers in principle benefit from the savings made through parallel imports, and that patients in the primary care sector also directly benefit from the savings through co-payments.

Table 1. Savings from parallel imports of pharmaceuticals in Denmark in 2021

		Primary sector	Hospital sector	Total
Total cost of pharmaceuticals (DKK million)	A	8,555	15,819	24,373
- of which costs of parallel-imported pharmaceuticals (DKK million)	B	2,595	1,207	3,802
Parallel importers' market share (%)	C = B/A	30%	8%	16%
Direct savings from parallel imports (DKK million)	D	367	33	399
Indirect savings from parallel imports (DKK million)	E	261	80	341
Total savings from parallel imports (DKK million)	**F = D+E**	**627**	**113**	**740**
Average saving on a parallel-imported pharmaceutical product (%)	G = F/(B+F)	19%	9%	16%
Total savings from parallel imports as a percentage of the total actual cost of pharmaceuticals (%)	H = F/A	7%	1%	3%

Note: All prices and savings are calculated on the basis of the PPP (pharmacy purchase price)
Sources: Copenhagen Economics, based on figures from Danish Pharmaceutical Information and the Danish Association of Parallel Importers of Pharmaceuticals and members

Savings in two scenarios with higher and lower market shares among parallel importers

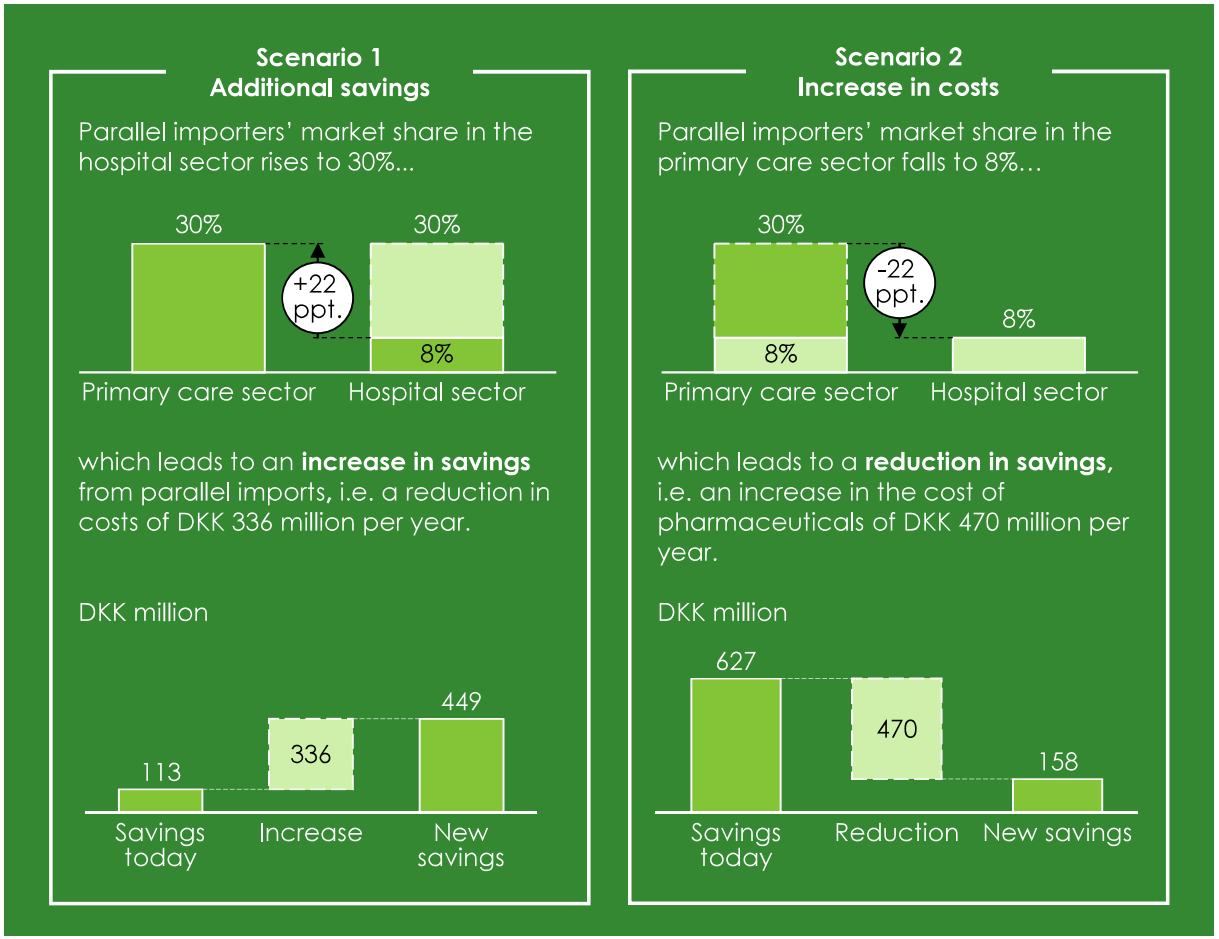
If the parallel importers' market share in the hospital sector of 8% rose to the same level as in the primary care sector (30%), public expenditure for pharmaceuticals would fall by DKK 336 million per year. If the opposite happened, the expenditure would rise by DKK 470 million a year.[1]

The differences between the parallel importers' market shares in the primary care and hospital sectors partly reflect regulatory differences between the sectors and the size of the entry barriers for parallel importers. Therefore, regulation plays a key role in determining the extent of the savings made.

In Figure 9 on the right, we have calculated what it would mean for the expenditure on pharmaceuticals if the parallel importers' market shares fell or rose to the current levels in each of the two sectors. In scenario 1, all additional savings would go towards improving public budgets. In scenario 2, the higher costs would be borne by both citizens and the public purse due to the co-payments at pharmacies.

The calculation of the scenarios is based on the assumption that the parallel importers' and original manufacturers' prices will remain unchanged despite the changes in market shares, and that the total volume traded in both sectors will remain unchanged. If the parallel importers experience limitations in the volumes of pharmaceuticals they can source at lower prices outside Denmark, it may prove difficult to realise the full potential savings.

Figure 9. Effect on costs of pharmaceuticals in scenarios with higher and lower market shares of parallel importers



Note: All prices and savings are calculated on the basis of the savings on PPP (pharmacy purchase price).
Source: Copenhagen Economics

1 The results of changes in parallel importers' market shares in the two scenarios comprise both direct and indirect savings. This means that, in the event of a change in market shares, we assume that the parallel importers will enter new markets or leave their existing markets; this will create or remove competition in these markets and have indirect effects.

2
SAVINGS IN THE PRIMARY CARE SECTOR

Savings from parallel imports of pharmaceuticals in the primary care sector

Total savings of DKK 627 million in the primary care sector

According to our calculations, the total savings made through parallel import of pharmaceuticals in the primary care sector in 2021 was DKK 627 million. Most of these savings were direct; cf. Figure 10.

Direct savings of DKK 367 million

The direct savings through parallel imports of pharmaceuticals in the Danish primary care sector in 2021 amounted to DKK 367 million. These savings reflect how much more the pharmacies would have paid for the pharmaceuticals they dispensed in 2021 if they had bought them at the prices the original manufacturers offered in the tenders; see Figure 11.

Indirect savings of DKK 261 million

In addition to direct savings, parallel imports also gives rise to indirect savings. These occur because the original manufacturers have an incentive to set their prices lower when there is competition from parallel importers. According to our calculations, in 2021 the indirect savings in the primary care sector amounted to DKK 261 million.

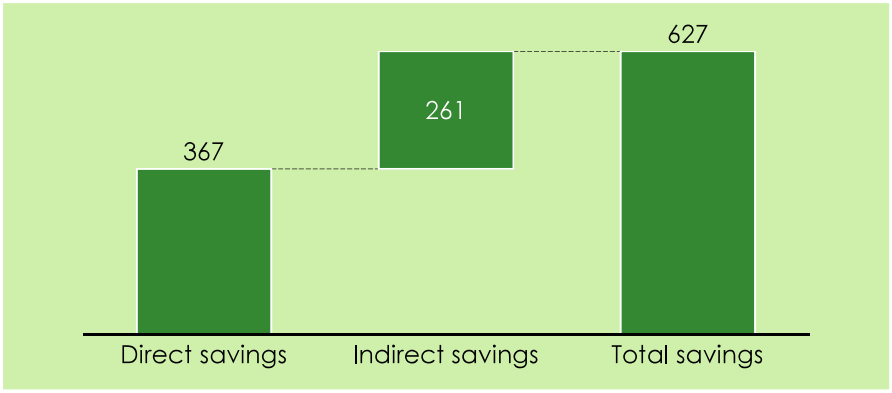
We have not calculated any further indirect savings on products where there is no competition from parallel importers, but where the possibility of competition in itself leads to lower prices among the original manufacturers.

Total savings of DKK 848 million in retail prices

All the above prices are stated in the unit of pharmacy purchase price (PPP). If we convert the total savings in the primary care sector to the total consumer price[1] or the pharmacy retail price that consumers actually pay at the pharmacy before subsidies, then the saving is DKK 848 million including VAT, of which the direct saving is DKK 496 million and the indirect saving is DKK 353 million.

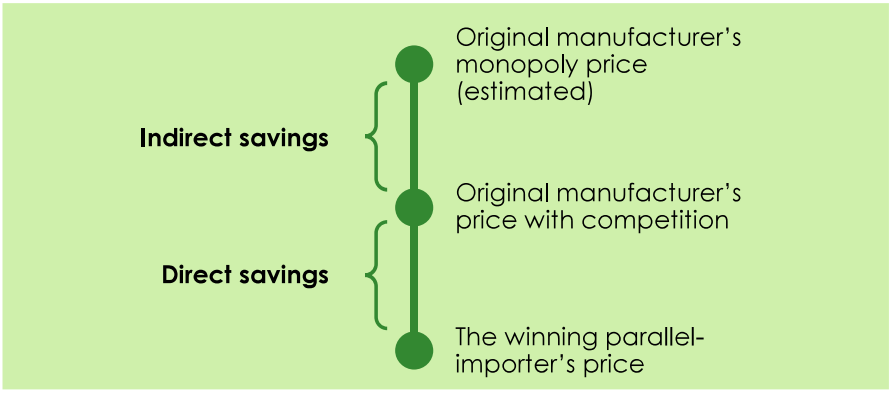
Figure 10. Savings from parallel imports of pharmaceuticals in the primary care sector in 2021

DKK million



Note: All prices and savings are calculated on the basis of the savings on the PPP (pharmacy purchase price).
Sources: Copenhagen Economics, based on information from Danish Pharmaceutical Information

Figure 11. Types of pricing related to parallel imports in the primary care sector



Source: Copenhagen Economics

1 The conversion to the total consumer price means that the savings in the pharmacy purchase price must be multiplied by 1.3525. The Danish Medicines Agency (2019), Conversion from pharmacy purchase price (PPP) to consumer price (ESP); see https://laegemiddelstyrelsen.dk/en/reimbursement/prices/conversion-to-consumer-price/

The regulation in the primary care sector provides good opportunities for parallel imports

The regulation in the primary care sector gives parallel importers good access to the market and the opportunity to take part in tenders. In contrast to the hospital sector, the obligation to supply in the primary care sector only lasts seven days, and there is no risk of fines in the event of failure to supply. This is part of the reason why parallel importers had a market share of 30% in 2021, corresponding to a turnover of more than DKK 2.5 billion.

The pricing of pharmaceuticals in the primary care sector takes place at fortnightly auctions

The prices of prescription drugs in the primary care sector, which are dispensed by Danish pharmacies, are determined at auctions every other Monday. This means that there is price competition in the primary care sector.

The suppliers review list prices once a fortnight and keeps them unchanged for the next 14 days. The pharmacies buy the medicine based on the list price or PPP (pharmacy purchase price). In these tenders, parallel importers can bid against original manufacturers on an equal footing.

The suppliers have a brief obligation to supply

As a general rule, a supplier that wins a tender in the primary care sector must supply the market for 14 days following the tender. The brief obligation to supply gives parallel importers good opportunities to participate in the tenders.

If a supplier fails to supply the product during the first week, the supplier will be excluded from the upcoming 14-day sales period. If the winning supplier fails to supply the product in the second week of the sales period and thus cannot meet the demand for the full 14 days, the pharmacies will begin to dispense the second-cheapest product from another supplier.

In practice, it is the pharmacies which, through their substitution obligation, take responsibility for ensuring that the cheapest alternative is dispensed to citizens.

The original manufacturers' prices do not contribute to overestimating the direct savings

One might imagine that an original manufacturer which always loses tenders to a parallel importer would decide to raise its price in Denmark so as to be better positioned in other countries where the original manufacturer's price depends on the price the original manufacturer sets in Denmark. For example through an external reference price system.

However, this is prevented by the fact that pricing in the primary care sector is regulated by voluntary agreements between the Danish Ministry of Health and the Danish Association of the Pharmaceutical Industry. Among other things, the current pricing agreement stipulates that the original manufacturers may not set their prices arbitrarily high.

This means that the original manufacturers' prices are the real alternatives in the competition with parallel imports, and suggests that the price differences between the original manufacturers and parallel importers can be interpreted as the direct saving achieved through parallel imports in the primary care sector.

Sources: Aftale mellem Lægemiddelindustriforeningen, Lif, Danske Regioner og Sundheds- og Ældreministeriet om loft over lægemiddelpriserne i perioden 1. april 2019 - 31. marts 2022; Association of Danish Pharmacies (Danmarks Apotekerforening) (2017), Høringssvar vedr. udkast til ændring af bekendtgørelse om Medicinpriser og leveringsforhold m.v.; Danish Competition and Consumer Authority (2017), Priscykler i markedet for receptpligtig medicin efter patentudløb; Cowi (2014), Analyse af indkøb af lægemidler i primærsektoren; Danish Competition and Consumer Authority (2016), Konkurrence om distribution af medicin

3
SAVINGS IN THE HOSPITAL SECTOR

Savings from parallel imports of pharmaceuticals in the hospital sector

Total savings of DKK 113 million in the hospital sector

According to our calculations, parallel imports of pharmaceuticals in the hospital sector resulted in savings of DKK 113 million in 2021. Most of these savings were indirect; cf. Figure 12.

We have estimated the original manufacturers' prices, as they are confidential. We work with four different prices, as shown in Figure 13. We know the original manufacturers' list prices, which we base our calculations on and correct downwards based on Amgros' average discounts on pharmaceuticals in 2018 in different competitive situations. Amgros lists an average discount on hospital-only pharmaceuticals in monopoly conditions of 14.6%[1], which we subtract from the list prices to obtain the original manufacturers' monopoly prices.

Indirect savings of DKK 80 million

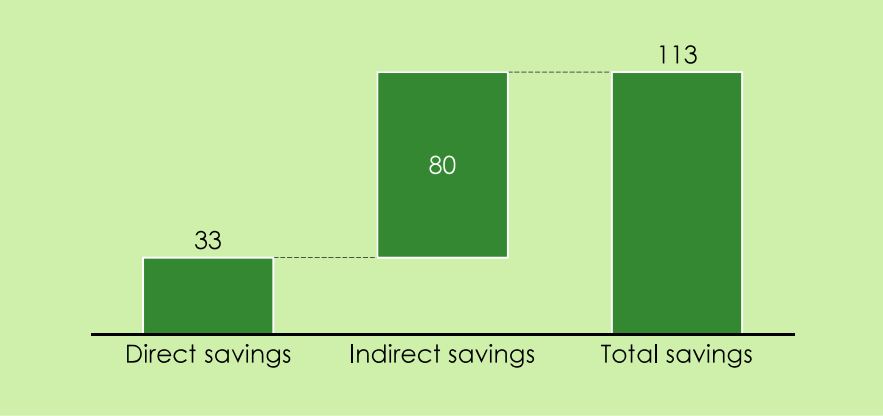
The indirect savings are determined from the difference between the original manufacturers' prices in monopoly conditions and in conditions of limited competition, where on average prices were 21.6% below the list price in 2018 according to Amgros.[1] We have not calculated any further indirect savings on products where there is no competition from parallel importers, but where the possibility of competition in itself leads to lower prices among the original manufacturers.

Direct savings of DKK 33 million

The direct savings are calculated as the difference between Amgros' average discount on hospital-only medicine with limited competition of 21.6% in 2018 and the winning parallel importer's price.

Figure 12. Savings from parallel import of pharmaceuticals in the hospital sector in 2021

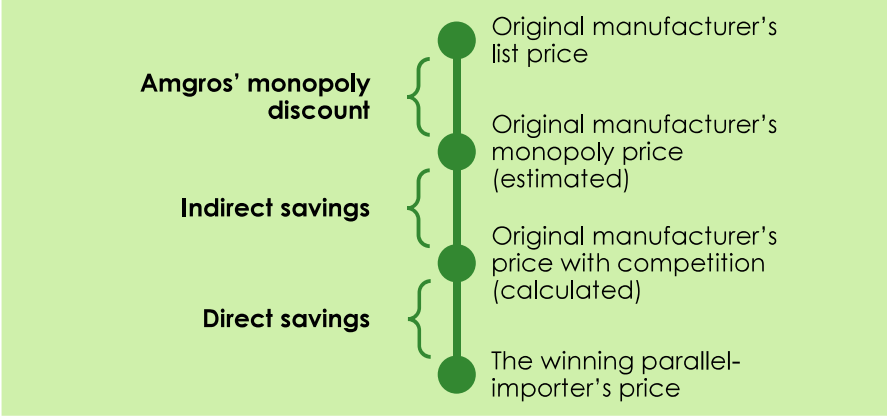
DKK million



Note: All prices and savings are calculated on the basis of the PPP (pharmacy purchase price)

Sources: Copenhagen Economics, based on figures from Amgros, the Danish Association of Parallel Importers of Pharmaceuticals and members

Figure 13. Types of pricing related to parallel imports in the hospital sector



Source: Copenhagen Economics

The regulation in the hospital sector limits parallel imports

The regulation in the hospital sector contributes to limiting parallel imports and thereby the competitive pressure on the original manufacturers. The tenders in the hospital sector typically involve one-year contracts, and the suppliers are faced with financial consequences in case they fail to supply the contracted amount. This may help explain why the parallel importers' market share in the hospital sector was only 8% in 2021, which corresponded to a turnover of DKK 1.2 billion.

According to the Danish Association of Parallel Importers of Pharmaceuticals, a number of adjustments to the regulation since 2018, in the form of increased flexibility have made it slightly more attractive for parallel importers to participate in hospital sector tenders. This may partly explain why the parallel importers' market share has increased by one percentage point from 2018 to 2021.

Pricing takes place through tenders with one-year contracts

Amgros is a purchasing organisation under the Danish regional administration. It buys approximately 99% of the pharmaceuticals used in Danish public hospitals.

Amgros' framework contracts typically apply for one year, but with the option of a one-year extension without a new tender.

Amgros carries out tenders and enters into contracts for a wide range of products. The criterion for winning a tender is either the lowest price or the most financially advantageous bid. Framework contracts may be entered into with one or more suppliers. Parallel framework contracts are concluded with up to five suppliers, which are ranked in such a way that it is the top-ranked supplier that has the obligation to supply the product.

Suppliers assume the risk in the form of a supply obligation

Suppliers of pharmaceuticals to Amgros assume an obligation to supply which triggers a financial cost in the event of a breach. It can be difficult for parallel importers to ensure supplies of pharmaceuticals for a full year at a specified price in advance. The one-year periods with an obligation to supply make the hospital sector less attractive for parallel importers compared with the primary care sector. This can, in turn, mean that some parallel importers do not participate in Amgros' tenders, leading to less intense competition in the tenders and a risk of higher prices.

If a supplier experiences a large number of backorders or for any other reason is not able to supply the product, the supplier is obliged to compensate Amgros for the additional cost by buying the cheapest possible replacement product.

The obligation to provide compensation for additional costs means that potential suppliers expose themselves to greater risk by participating in tenders for the hospital sector than they do by participating in tenders for the primary care sector. These risks may be particularly significant for parallel importers.

Parallel importers cannot always predict how much medicine they will be able to buy in the rest of the EU/EEA, nor do they necessarily know the prices of the medicine for the next 12 months. In terms of Amgros tenders, both these factors are disadvantages for the parallel importers in relation to the original manufacturers, which have control of their production, and presumably also more stable costs.

Long contracts have mixed effects on competition

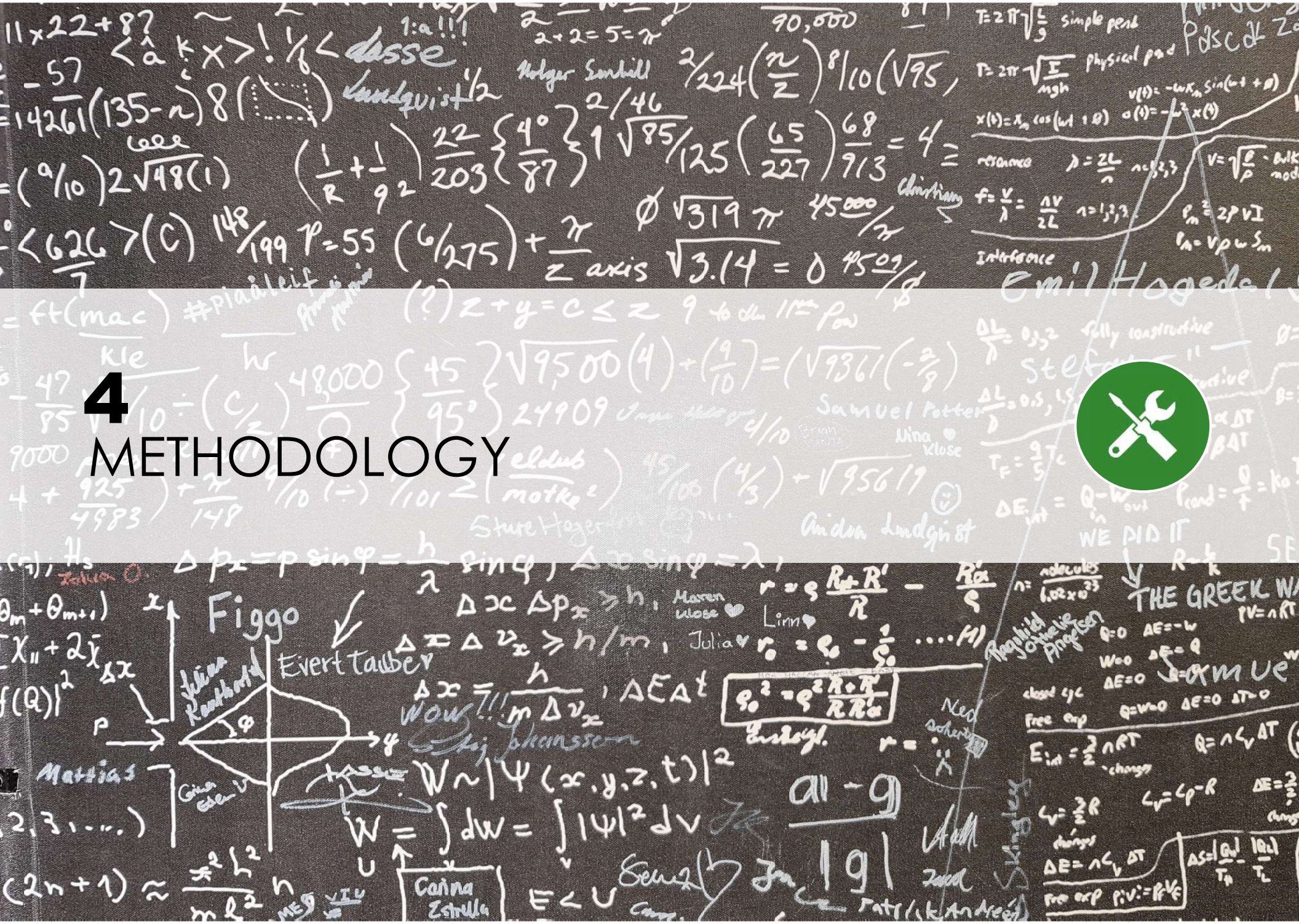
The tender contracts are significantly longer in the hospital sector than in the primary care sector, which means that the tender winner secures the market for longer. This can give bidders more incentive to set a low price. However, the longer contracts and stricter supply obligations also mean that fewer suppliers bid in the tenders. If the loser of a tender fully withdraws from the market, it may limit competition for contracts.

The list prices in the hospital sector are regulated by voluntary agreements between the Danish Ministry of Health, the Danish Association of the Pharmaceutical Industry and the Danish Regions.

The rising cost of pharmaceuticals is mainly driven by the hospital sector

The costs of hospital pharmaceuticals rose by almost 23%, to DKK 15.8 billion, between 2018 and 2021; see Figure 2. In the same period, costs of primary sector pharmaceuticals rose by less than 16%, to DKK 8.6 billion. This means that the hospital sector mainly drives the current increases in the costs of pharmaceuticals. It is also in the hospital sector that parallel imports of pharmaceuticals have a relatively small market share.

Sources: Danish Competition and Consumer Authority (2018), CD Pharmas prissætning af Syntocinon; Aftale mellem Lægemiddelindustriforeningen, Lif, Danske Regioner og Sundheds- og Ældreministeriet om loft over lægemiddelpriserne i perioden 1. april 2019 - 31. marts 2022; Cowi (2014), Analyse af indkøb af lægemidler i primærsektoren; Danish Competition and Consumer Authority (2016), Konkurrence om distribution af medicin



4
METHODOLOGY

Methodology

Comparison between factual and counterfactual costs of pharmaceuticals

In the analysis, we calculate the savings made through parallel imports in Denmark in 2021.

We do this by comparing the actual costs with counterfactual costs that would have been incurred in the absence of parallel imports. In the calculations we distinguish between direct and indirect savings. The direct savings occur when the parallel importer places a lower priced bid than the original manufacturer. The indirect savings occur because the original manufacturer reacts to the parallel importer entering the market by reducing its price.

We have calculated the direct savings by comparing the actual costs with the volumes sold by the parallel importers and the prices placed in bids by the original manufacturers.

We calculate the indirect savings by comparing the prices placed in bids by original manufacturers with the estimated bids of original manufacturers in the absence of competition from parallel importers.

Price units

All prices in the analysis are stated according to the pharmacy purchase price (PPP). This means that the immediate savings for consumers are greater than those specified in the calculations. At the pharmacies, the medicine is dispensed at the total consumer price, i.e. the price that the consumers actually pay, which includes VAT, among other things.[1]

The next four slides explain the methodology employed in the primary care and hospital sectors in more detail.

1 The Danish Medicines Agency (2019), Conversion from pharmacy purchase price (PPP) to consumer price (ESP); see https://laegemiddelstyrelsen.dk/en/reimbursement/prices/conversion-to-consumer-price

Methodology in the primary care sector

We use substitution groups to calculate direct and indirect savings

The Danish pharmacies buy primary sector pharmaceuticals from the original manufacturers or parallel importers via wholesalers through fortnightly tenders. As a general rule, the pharmacies then dispense the cheapest product within each substitution group for the next 14 days. A substitution group contains medicine that has the same effect, for example the original manufacturer's and a parallel importer's equivalent product. The organisation of the products into substitution groups allows us to match the original manufacturers and the parallel importers, which is necessary for our calculation.

Contents of the data set

The data set we use for our calculations is drawn from Danish Pharmaceutical Information and we have received it from the Danish Association of Parallel Importers of Pharmaceuticals. The dataset contains information about turnover, volumes and prices for each tender held in the period 2008-2021 by item number and with information on the product's substitution group.

Data cleaning

Our results are based on data from 665 substitution groups. In our calculations, we omit substitution groups where:

- There is no parallel import
- There is incorrect data, e.g. where parallel imports and generics are listed as being from the original manufacturer
- We delete observations with missing price data, volumes or item numbers.

In addition, in each substitution group, we correct for a few observations with negative volumes by subtracting the number of negative volumes sold from the total volume sold in 2021.

Calculation method for direct savings from parallel imports

To calculate the savings that parallel imports of pharmaceuticals gave rise to in the primary care sector in 2021, we compare the total cost of the parallel-imported primary sector pharmaceuticals in Denmark in 2021 with the cost that would have been incurred in a situation without parallel importers, given the observed prices bids by original manufacturers. In other words, we assume that the same volumes would have been sold at the original manufacturers' prices.

We calculate the indirect savings as the difference between the original manufacturer's actual price and the estimated counterfactual price set by the original manufacturer in the absence of parallel imports multiplied by the total volume sold in the substitution group. See the calculation methodologies for both direct and indirect savings below, and the methodology for estimating the original manufacturer's price in the absence of parallel imports on the next page.

$$Direct\ savings = (Price_{original\ manufacturer} - Price_{parallel\ importer}) \times volume_{parallel\ importer}$$

$$Indirect\ savings = (Price_{counterfactual} - Price_{original\ manufacturer}) \times (volume_{original\ manufacturer} \times volume_{parallel\ importer})$$

Methodology in the primary care sector

We estimate the original manufacturer's price in the absence of parallel imports in order to calculate indirect savings

The presence of parallel imports in a substitution group may cause the original manufacturer to react by changing its price. It is this reaction that leads to what we call indirect savings. To calculate the size of these indirect savings, we firstly have to estimate the original manufacturer's price in the absence of parallel imports, as this price is counterfactual and therefore not directly observable.

Our approach to estimating this price is to take the average price over one year or 27 tenders before a parallel importer enters the market, as shown in Figure 14 below.

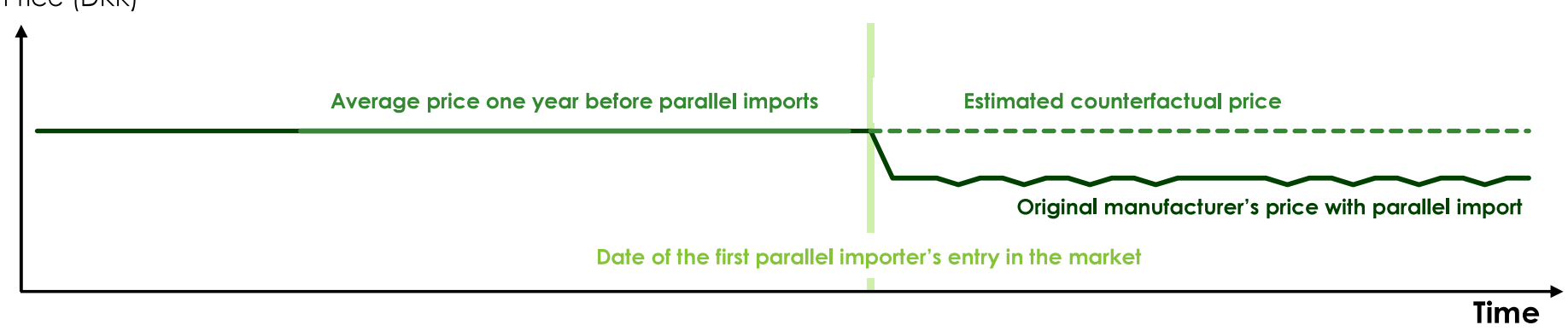
By using the average price over a period of a whole year, we ensure that possible outliers in the data do not define the original manufacturer's monopoly price, and that we do not thereby misjudge the indirect savings.

Some products have been subject to competition from parallel imports throughout the period since 2008, and therefore do not have a prior period that we can use to estimate the price in the absence of parallel imports. For these products, we assume an effect on the original manufacturer's price of parallel imports that corresponds to the average effect in the dataset.

Assumption

Our calculation for the primary care sector is based on an assumption of inelastic demand for medicines. In other words, we assume that the same quantities of medicines would have been sold in 2021 in the absence of parallel imports.

Figure 14. Illustration of method for estimating the original manufacturer's price in the absence of parallel imports



Note: The figure is solely intended to illustrate the method.
Source: Copenhagen Economics

Methodology in the hospital sector

We calculate savings in the hospital sector analogously with savings in the primary care sector

In terms of method, our calculation of the savings in the hospital sector follows our calculation of savings in the primary sector, as described above. Although the calculations are conceptually similar, there are a few significant differences in how we calculate the savings in practice. In the following, we describe these differences.

For the hospital sector, we only calculate the indirect savings for the periods when parallel importers won the tender. We do this mainly because we lack data on sales in periods when the original manufacturer won the tender. This is a conservative approach to calculating the indirect savings in the hospital sector. In practice, the presence of parallel imports may affect the original manufacturer's bid, even in periods when the parallel importer does not win the tender. In these cases, all else equal, we underestimate the indirect savings.

We use data on prices and volumes from Danish parallel importers

We have received datasets on four parallel importers: 2care4, Abacus Medicine, Orifarm, and Paranova. The data sets contain the parallel importers' prices and volumes sold, as well as the original manufacturers' list prices.

We estimate the original manufacturer's bid based on Amgros' average discounts

We do not have access to the original manufacturer's bids, and therefore have to estimate them when we calculate the direct effects. This also means that we cannot use the same method to calculate the counterfactual price as we do for the primary sector, which the original manufacturer had bid in the absence of parallel imports, and which we have to use when calculating indirect effects.

When it comes to the original manufacturers' list prices, Amgros obtained the following discounts on hospital pharmaceuticals in 2018[1]:

- Monopoly: 14.6%
- Limited competition: 21.6%

We estimate the original manufacturer's bid by downscaling their list price by Amgros' average discount in a situation of limited competition. The difference between the estimated bid of the original manufacturer and the parallel importer's price then forms the basis for the calculation of the direct savings.

Thereafter, we estimate the original manufacturer's bid without parallel imports by correcting the original manufacturer's list price using Amgros' average discount under monopoly conditions. The difference between this estimated bid under monopoly conditions and the estimated bid under conditions of limited competition forms the basis for the calculation of the indirect savings.

Note that Amgros' average discounts are calculated across all hospital-only pharmaceuticals, which we assume also applies specifically to the products where there is competition from parallel importers.

We use average discounts obtained by Amgros in 2018. There is more recent data available that we choose not to use for two reasons. First, Amgros' average monopoly discount is higher than under conditions of limited competition in the more recent data. We find this result odd, as competition usually leads to lower prices. Secondly, the discounts in the new data are so high that in most cases the estimated bids of the original manufacturers would be lower than the observed bid from the parallel importer. Since parallel importers by definition only win tenders when they bid the lowest price, this result does not make sense. According to Amgros, possible explanations include that the average discount on the original manufacturers' list prices is relatively large for new advanced therapies (ATMP), which parallel importers in Denmark do not sell, as well as innovative agreements where Amgros' expense is independent of the quantity consumed, which is also not a form of cooperation that the parallel importers in Denmark have adopted. Since these developments – which have contributed to increasing the average discounts calculated on the basis of the original manufacturers' list prices – are not representative of the parallel importers in Denmark, we consider it most accurate to base our calculations on Amgros' average discounts for 2018.

Dynamic effects only influence the results on savings marginally

In this analysis, we calculate savings made from parallel imports of pharmaceuticals in Denmark in 2021. For this purpose, we have assumed an inelastic demand for pharmaceuticals, and that the parallel imports' effect on the original manufacturers' strategic behaviour is marginal.

We describe our considerations about the dynamic effects below.

We assume inelastic demand

In our calculations of the savings in the primary care and hospital sectors, we compare the factual turnover of parallel importers with a counterfactual scenario in which the same amount is sold at higher prices by original manufacturers. This means that we assume the demand for pharmaceuticals is inelastic. In other words, we assume that the volume traded is unaffected by the price level.

When the price of a product rises, it will usually lead to a fall in the volume traded.[1] Our assumption that this is not the case with pharmaceuticals is based on the fact that, in the hospital sector, there is a disconnection between doctors who prescribe medicine according to the patients' needs and the public payment. In the primary care sector, there is a partial disconnection, since only about 30% of the consumption is paid by the patients,[2] but here too the need is determined by doctors.

If we had assumed an elastic demand, the immediate savings would have been smaller, but in that case there would also have been patients who would not have received the medicine they were actually treated with in 2021. For the same reason, it would be much more complex to compare with a counterfactual scenario in which both the prices and traded volumes were changed, as there could also be health-related effects.

Marginal effect on the original manufacturers' strategic behaviour

The profits of the original manufacturers may decrease as a result of parallel import of pharmaceuticals. The reason for this is that parallel imports limit the original manufacturers' ability to price products differently in different EU/EEA countries.

If the original manufacturers' profit falls as a result of parallel imports, it may lead them to change their behaviour. There are two main types of decisions made by the original manufacturers which may be affected.

Firstly, parallel imports can reduce the original manufacturers' incentive to invest in and develop new pharmaceuticals if the parallel imports have sufficient scope to affect the original manufacturers' financial business case for investing in new pharmaceuticals.

Secondly, parallel imports may give the original manufacturers an incentive to change their decisions on launching and pricing pharmaceuticals in the EU/EEA countries where the parallel importers buy products for resale in Denmark. If the original manufacturers know which countries the parallel importers buy their products in, this can provide an incentive to set a higher price in these countries to prevent parallel imports. In addition, parallel imports can give the original manufacturers an incentive to postpone or not to market a product in countries where the parallel importers source their products, in order to prevent parallel imports.

Given that Denmark makes up a very small share of the global market for pharmaceuticals – so that lower turnover in Denmark has little influence on an original manufacturer's overall earnings – parallel imports of pharmaceuticals in Denmark in 2021 only gave original manufacturers a very small incentive to change their behaviour, as described above.

If this analysis were repeated on a European or global level, and if the savings were to be calculated for a future period of several years, a reliable result concerning savings would have to take into account dynamic effects in the form of the original manufacturers' strategic behaviour.

1 World Health Organization – Pharmaceutical pricing policy; see apps.who.int/medicinedocs/documents/s19585en/s19585en.pdf
2 Amgros (2019) Markedet og årsslides

The economic impact of parallel imports of pharmaceuticals

An assessment of savings in Denmark in 2021

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