

THE ECONOMIC IMPACT OF PARALLEL IMPORTS OF PHARMACEUTICALS

An assessment of savings in
Denmark

The Danish Association of Parallel Importers of Pharmaceuticals
2019



Introduction

The Danish Association of Parallel Importers of Pharmaceuticals (Foreningen for Parallelimportører af Medicin) has asked Copenhagen Economics to calculate the savings that parallel imports of pharmaceuticals led to in Denmark in 2018. The calculation concerns primary sector pharmaceuticals dispensed at pharmacies as well as hospital sector pharmaceuticals.

To carry out the analysis for the primary care sector, we received data on traded volumes and prices from The Danish Association of Parallel Importers of

Pharmaceuticals. As regards savings in the hospital sector, we have based our calculations on data on traded volumes and prices from 2care4, Abacus Medicine and Orifarm.

In addition, we have carried out a literature review, conducted interviews with six experts and researchers in health economics, and consulted with public authorities in the field.

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.

The conclusions of the analysis are exclusively those of Copenhagen Economics and do not necessarily reflect the opinions of the project's interviewees or partners. Copenhagen Economics is also responsible for the calculations and data processing.

Contributors to the analysis

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The analysis was carried out independently by Copenhagen Economics.

2care4

ABACUS MEDICINE

ORIFARM

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

FPM

Foreningen for
Parallelimportører af Medicin

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

Summary

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

According to our calculations, the total savings from parallel import of pharmaceuticals in 2018 amounted to DKK 610 million, or 3% of the total expenditure on pharmaceuticals in Denmark.

The analyses in this report are based on two data sets showing volumes, prices and expenditure on pharmaceuticals in Denmark in 2018. One data set covers primary sector pharmaceuticals, i.e. medicine dispensed in pharmacies, and another data set covers hospital sector pharmaceuticals.

Parallel import of pharmaceuticals leads to savings

We find that the total savings from parallel import of pharmaceuticals in 2018 amounted to DKK 610 million, calculated on the basis of the pharmacies' purchase prices (PPP), see Figure 1. This corresponds to 3% of the total expenditure on pharmaceuticals in Denmark, or an average saving on parallel-imported products of 17%.

Most savings occur in the primary care sector, where they amount to DKK 545 million, and where the parallel importers have a market share of 26%. In the hospital sector, where the parallel importers' market share is 7%, the corresponding savings are

DKK 65 million. This is partly due to parallel import of pharmaceuticals being more widespread in the primary care sector than in the hospital sector.

Parallel import of pharmaceuticals leads to direct and indirect savings. The direct savings can be observed and amount to DKK 234 million, which reflects the price difference between the cheapest parallel imported medicines and the original manufacturer's. The indirect savings are calculated and amount to DKK 376 million, which reflects the difference between the original manufacturers' calculated monopoly prices and the observed prices when there is competition from parallel importers. In other words, the existence of parallel importers incites lower prices among the original manufacturers.

The amount of savings depends on the conditions for parallel imports

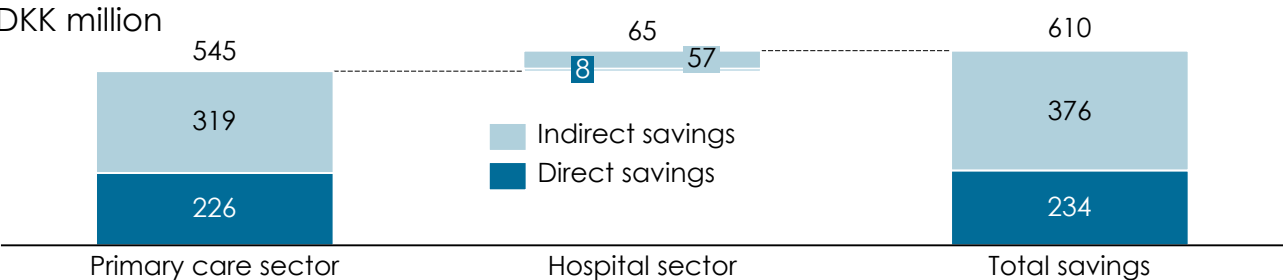
The relatively large savings in the primary care sector of DKK 545 million are partly due to the fact that parallel import of pharmaceuticals benefits from a more supportive regulatory environment in this sector than in the hospital sector.

In a scenario in which the parallel importers' market share in the primary care sector fell to 7%, as in the hospital sector (for instance if the conditions came to resemble those in the hospital sector), the expenditure on pharmaceuticals in Denmark would increase by DKK 400 million, corresponding to almost two thirds of the total savings in 2018.

Conversely, in a scenario in which the parallel importers' market share increased to 26% in the hospital sector (for instance if the conditions came to resemble those in the primary care sector), the expenditure would fall by a further DKK 179 million, bringing the total savings achieved through parallel imports up to approximately DKK 789 million.

The two scenarios show that the size of the savings depends on the conditions for parallel imports. There is a potential for the savings to become larger than they are today, but at the same time, the existing savings can only be realised as long as the conditions allow for and support parallel import of pharmaceuticals.

Figure 1. Savings from parallel import of pharmaceuticals in 2018



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

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PARALLEL IMPORT OF PHARMACEUTICALS IN DENMARK



What is parallel import of pharmaceuticals?



Parallel-imported pharmaceuticals are original medicinal products imported from an EU/EEA country¹ where they are cheaper than in Denmark. They are the same medicinal products as the ones sold by the manufacturer itself 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 expenditure on pharmaceuticals in the primary care and hospital sectors in Denmark in 2014 and 2018, as well as the extent of parallel imports. In both sectors, the expenditure of both originally produced and parallel-imported pharmaceuticals increased over the period, although the overall increase in the primary care sector was very limited.

Parallel import of pharmaceuticals has taken place in

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

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

The price differences give parallel importers opportunities to buy pharmaceuticals in a country where the prices are lower in order to resell them at a

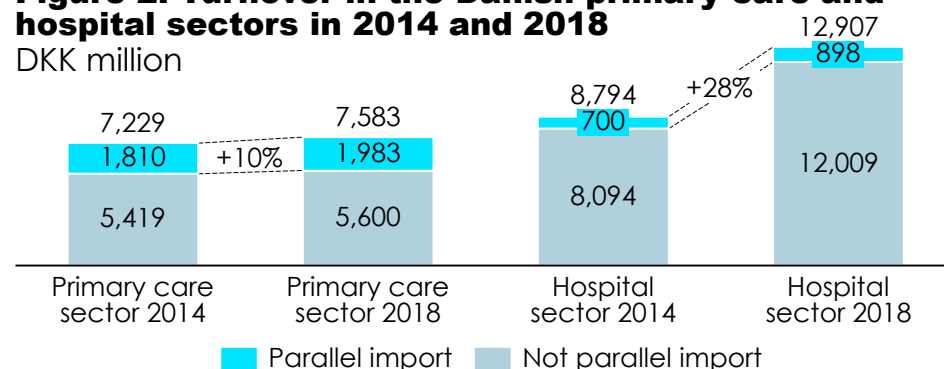
profit in countries where the prices are higher. If there are several parallel importers in the same country which sell the same pharmaceuticals, they will be in competition with each other, which further contributes to reducing prices.

Parallel imports most often 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 import of pharmaceuticals can be found on the Danish Medicines Agency's website under 'Guidelines on parallel import'.⁴

Figure 2. Turnover in the Danish primary care and hospital sectors in 2014 and 2018

DKK million



Note: All prices and savings are calculated on the basis of the savings on PPP (pharmacy purchase price)
Source: Danish Drug 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 fpmdk.dk/QA.html

³ Ulrika Enemark (2006), The economic impact of parallel import of pharmaceuticals

⁴ Danish Medicines Agency – guidelines no. 9170 of 27 February 2018; see <https://laegemiddelstyrelsen.dk/en/licensing/licensing-of-medicines/parallel-import/guidelines-on-parallel-import>

The value chain for parallel import of pharmaceuticals in Denmark



When patients in Denmark are given primary sector pharmaceuticals in pharmacies, it may come from an original manufacturer or a parallel importer. Parallel imports occur when pharmacies in Denmark can purchase a parallel-imported product at a lower price than the price of a corresponding product from the original manufacturer.

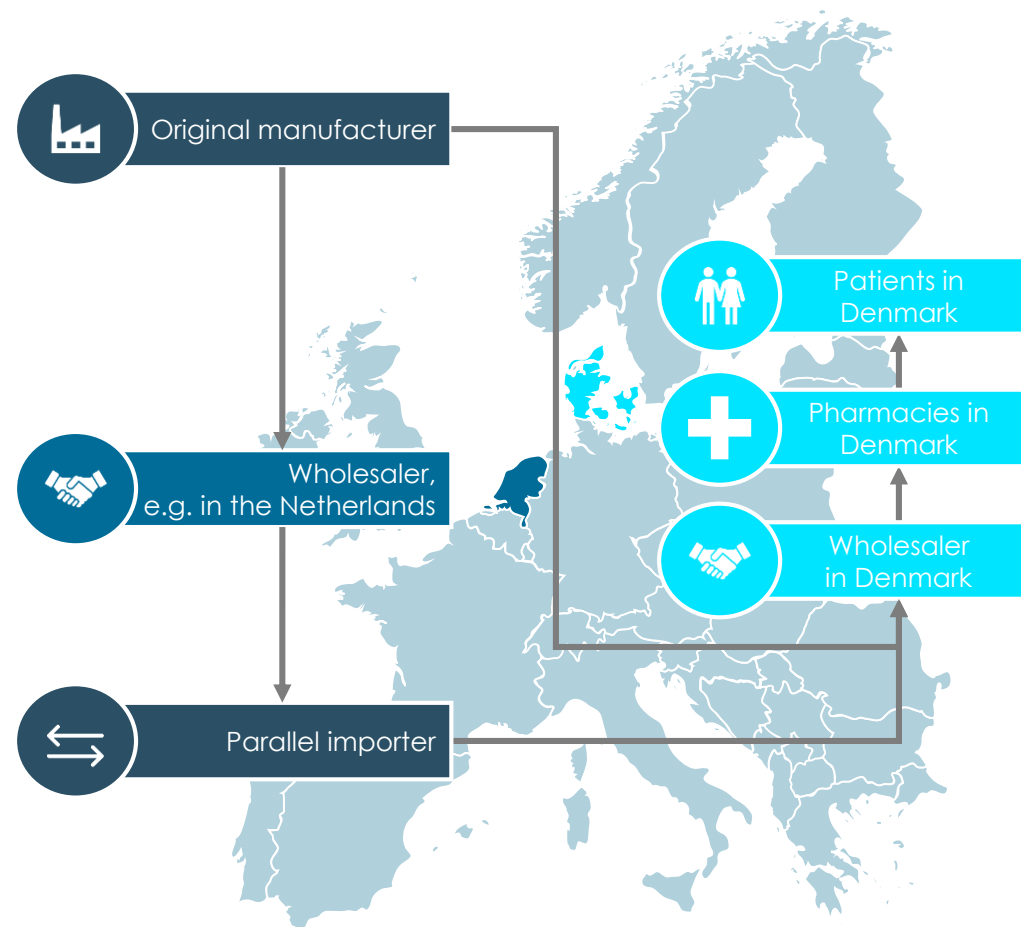
In the example in Figure 4 on the right, this means that patients will receive parallel-imported pharmaceuticals when:

*The price charged by the original manufacturer to a wholesaler in the Netherlands
+ the Dutch wholesaler's profit
+ the parallel importer's profit
+ the Danish wholesaler's profit
is lower than:
the price charged by the original manufacturer to a wholesaler in Denmark
+ the Danish wholesaler's profit.*

In this example, the parallel importer purchases its products from a wholesaler situated in the Netherlands. In practice, parallel importers buy products throughout the entire 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 the 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*

Direct and indirect savings from parallel import of pharmaceuticals



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

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

Primary care sector

We calculate the direct savings on a product in the primary care sector as the price difference between a parallel importer's winning bid, at which price the product has been sold, and the higher bid of the original manufacturer in the same tender, which hasn't generated revenue. We then aggregate the savings across all products in the volumes that were sold by parallel importers in 2018.

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 data set containing the original manufacturers' prices in 131 tenders¹ from 2014 to 2018, and calculate a moving average over one-year periods or 27 tenders.² We then interpret the difference between the highest price in the moving average and the actual prices as the original manufacturers' response to the competition from parallel importers, which are the indirect savings. The indirect savings are as real as the direct savings, but their magnitudes are subject to more uncertainty, since the prices under monopoly conditions by definition cannot be observed, but must be calculated.

Hospital sector

We calculate the overall savings in the hospital sector by comparing the parallel importers' sold volumes

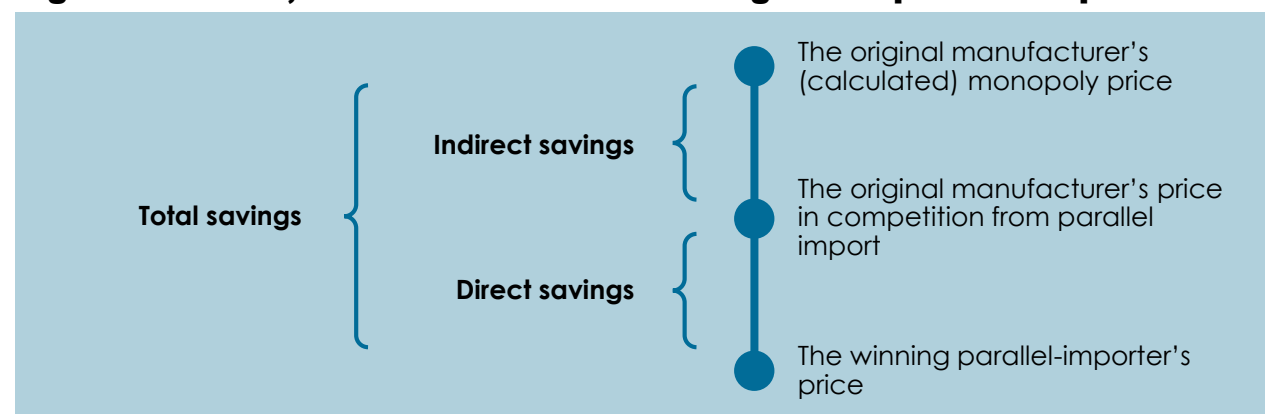
and prices with the original manufacturers' list prices, minus a discount of 14.6%³, which Amgros on average obtains for hospital-only monopoly products. We calculate the original manufacturers' prices, since they are confidential and we do not have direct access to them.

We separate the direct savings by comparing the savings on parallel import of 22.6% with the original manufacturers' list prices with a discount of 21.6%, which Amgros on average obtains for hospital-only products with limited competition. 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. The average price of the corresponding parallel-imported product is DKK 77.40, which corresponds to a saving of 22.6% compared with the original manufacturer's list price. Thus the direct saving is DKK 1, which is the difference between the parallel importer's price and the original manufacturer's price in competitive conditions, and the indirect saving of DKK 7 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 For each of the 131 tenders, the data set contains the original manufacturers' price bids in 618 substitution groups

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

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



The savings achieved through parallel import of pharmaceuticals in Denmark have previously been analysed. The previous analyses have focused exclusively on savings in the primary care sector, where we find the biggest savings. The previous analyses have found savings in the range of DKK 22-396 million per year, see Figure 6.

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 variation in the methodologies.

P. Kanavos (2004) especially stands out by employing a particular methodology which gives rise to relatively low savings compared to the other

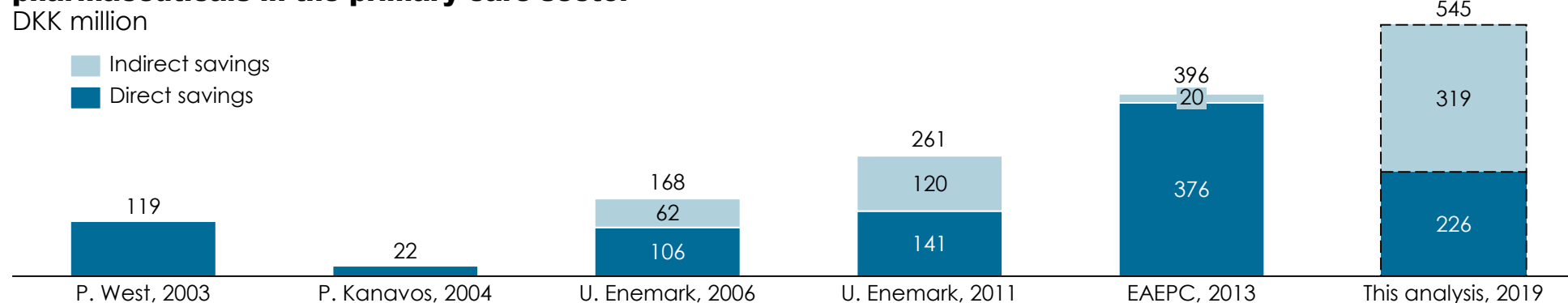
analyses. For example, the savings in Denmark are based on just 14 products, and for most of the products the parallel importers had market shares of less than 20%. In this way, the relatively small savings are a consequence of the methodology. A few years after the publication of this analysis, U. Enemark (2006) reviewed and rejected the methodology employed by P. Kanavos, and none of the two later analyses employed P. Kanavos's methodology. Due to the above considerations, neither do we.

The methodology employed by the present analysis 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 three most recent analyses cover both direct and indirect savings, while the first two analyses covered direct savings only.

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 6. This and previous analyses' years and results regarding savings from parallel import of pharmaceuticals in the primary care sector



Note: All prices are specified as in the sources and have not been adjusted for e.g. inflation. 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; EAEP (2013), The Parallel Distribution Industry – A closer look at savings

Competition between parallel importers contributes to lower prices



On average, parallel import of pharmaceuticals in Denmark gives rise to savings of 17%. These savings can be attributed to the presence of several parallel importers, whose competition drives the prices below the original manufacturers' prices.

The 17% saving obtained through parallel imports reflects an average saving in the primary care and hospital sectors of 22% and 7%, respectively, in relation 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 a 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 import of pharmaceuticals require competition between parallel importers.²

In Denmark, four parallel importers cover

approximately 99% of the Danish market for parallel import of 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.

Overall savings from parallel imports of DKK 610 million in 2018



We find that the total savings resulting from parallel import of pharmaceuticals in 2018 was DKK 610 million, see Table 1. The largest part of the savings – DKK 545 million – occur in the primary care sector, on medicine dispensed in pharmacies. The remaining savings of DKK 65 million are made through the purchase of pharmaceuticals for the hospital sector.

The total savings of DKK 610 million correspond to 3% of the total expenditure on pharmaceuticals in Denmark of DKK 20.5 billion. The savings occur because, on average, parallel-imported

pharmaceuticals are 17% 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 14%, which reflects a relatively high market share in the primary care sector of 26% and a lower market share of 7% in the hospital sector.

The savings made through parallel import of

pharmaceuticals in the hospital sector accrue to the healthcare service, while the savings in the primary care sector accrue to both the healthcare service and the Danish patients due to their co-payments amounting to around 30% of the expenditure.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 from co-payments.

Table 1. Savings from parallel import of pharmaceuticals in Denmark in 2018

		Primary sector pharmaceuticals	Hospital sector pharmaceuticals	Total
Total expenditure on pharmaceuticals (DKK million)	A	7,583	12,907	20,490
- of which expenditure on parallel-imported pharmaceuticals (DKK million)	B	1,983	898	2,882
Parallel importers' market share (%)	C = B/A	26%	7%	14%
Direct savings from parallel imports (DKK million)	D	226	8	234
Indirect savings from parallel imports (DKK million)	E	319	57	376
Total savings from parallel imports (DKK million)	F = D+E	545	65	610
Average saving on a parallel-imported pharmaceutical (%)	G = F/(B+F)	22%	7%	17%
Total savings from parallel imports in % of the total actual expenditure on pharmaceuticals (%)	H = F/A	7%	1%	3%

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

Two scenarios for savings: Higher and lower market shares among parallel importers



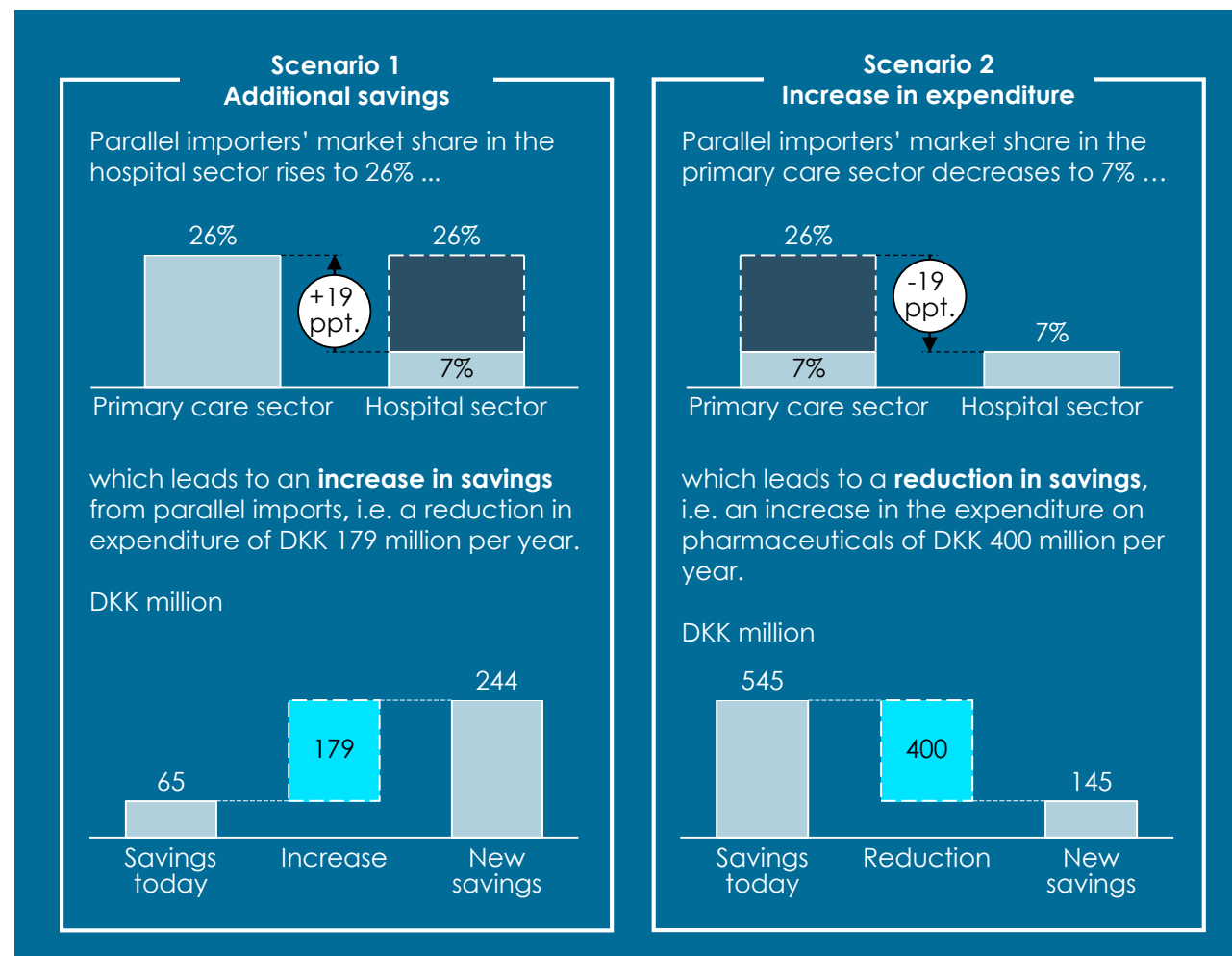
If the parallel importers' market share in the hospital sector of 7% rose to the same level as in the primary care sector (26%), public expenditure on pharmaceuticals would decrease by DKK 179 million per year. If the opposite happened, the expenditure would increase by DKK 400 million per year.¹ This would amount to more than the savings that Amgros is making due to the patent expiration of the world's most sold medicine, Humira, in 2018.²

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 7 on the right, we have calculated what it would mean for the expenditure on pharmaceuticals if the parallel importers' market shares rose or fell 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 expenditure would be borne by both citizens and the public budget 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. In case parallel importers experience limitations in the volumes of pharmaceuticals they can buy at lower prices outside Denmark, it may prove difficult to realise the full potential savings.

Figure 7. Effect on pharmaceutical expenditure in scenarios with higher and lower market shares among 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 Amgros (2018), Nu kan dyr medicin erstattes: Regioner kan spare flere hundrede mio. kr. årligt

2

SAVINGS IN THE PRIMARY CARE SECTOR



Savings from parallel import of pharmaceuticals in the primary care sector



Total savings of DKK 545 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 2018 was DKK 545 million. Most of these savings were indirect, see Figure 8.

Direct savings of DKK 226 million

The direct savings from parallel import of pharmaceuticals in the Danish primary care sector in 2018 amounted to DKK 226 million. These savings reflect how much more the pharmacies would have paid for the pharmaceuticals they dispensed in 2018 if they had bought them at the prices the original

manufacturers offered in the tenders. See Figure 9.

Indirect savings of DKK 319 million

In addition to direct savings, parallel import also gives rise to indirect savings. These occur because the original manufacturers would have an incentive to set their prices higher if there was no competition from parallel importers. According to our calculations, the indirect savings in the primary care sector amounted to DKK 319 million in 2018.

We have not calculated any further indirect savings on products where there is no competition from parallel importers, even if the possibility of

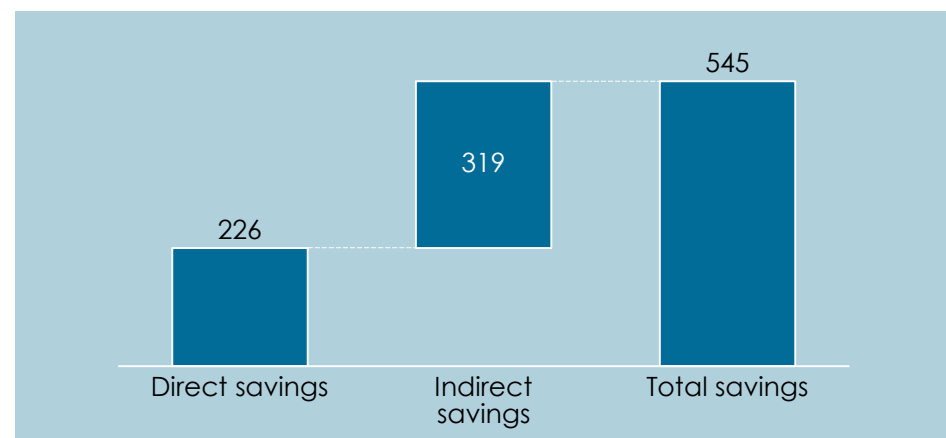
competition in itself leads to lower prices among the original manufacturers.

Total savings of DKK 737 million in retail prices

All the above prices are stated according to the pharmacy purchase price (PPP). If we convert the total savings in the primary care sector to the total consumer price¹ or the pharmacy retail price that consumers actually pay at the pharmacy before subsidies, then the saving is DKK 737 million including VAT, of which the direct saving is DKK 306 million and the indirect saving is DKK 431 million.

Figure 8. Savings obtained through parallel import of pharmaceuticals in the primary care sector in 2018

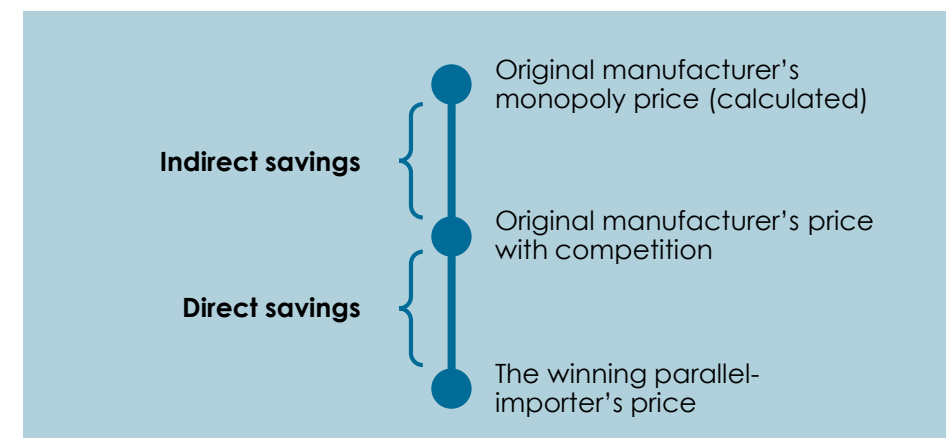
DKK million



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

Sources: Copenhagen Economics, based on Danish Drug Information

Figure 9. Types of pricing related to parallel imports in the primary care sector



Source: Copenhagen Economics

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



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 supply obligation in the primary care sector is just seven days, and there is no risk of fines in the event of a supply failure. This is part of the reason why parallel importers had a market share of 26% in 2018, corresponding to almost DKK 2 billion.

The pricing of primary sector pharmaceuticals takes place at fortnightly auctions

The prices of prescription drugs in the primary care sector, which are dispensed at Danish pharmacies, are determined at auctions every second 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). The parallel importers can bid on an equal footing with original manufacturers.

The suppliers have a brief supply obligation

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 supply obligation 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 the 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 with parallel import competition, 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 Lægemeddelindustriforeningen, Lif, Danske Regioner og Sundheds- og Ældreministeriet om loff 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 import of pharmaceuticals in the hospital sector



Total savings of DKK 65 million in the hospital sector

According to our calculations, parallel import of pharmaceuticals in the hospital sector resulted in savings of DKK 65 million in 2018. Most of the savings are indirect, see Figure 10.

We have calculated the original manufacturers' prices, as they are confidential. We work with four different prices, as shown in Figure 11. We know the original manufacturers' list prices, which we base our calculations on and correct for the average discounts Amgros obtains on pharmaceuticals in different

competitive settings. 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 57 million

The indirect savings are determined as the difference between the original manufacturers' prices in monopoly conditions and in limited competition, where on average prices are 21.6% below the list price according to Amgros.¹

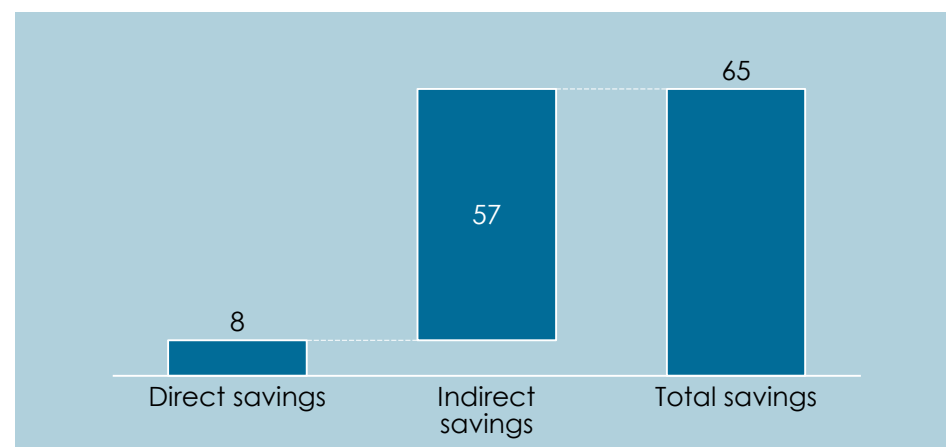
We have not calculated any further indirect savings on products where there is no competition from parallel importers, even if the possibility of competition in itself leads to lower prices among the original manufacturers.

Direct savings of DKK 8 million

The direct savings are calculated as the difference between Amgros's average discount on hospital-only medicine with limited competition of 21.6% and the winning parallel importer's price, which on average is 22.6% below the original manufacturers' list prices.

Figure 10. Savings obtained through parallel import of pharmaceuticals in the hospital sector in 2018

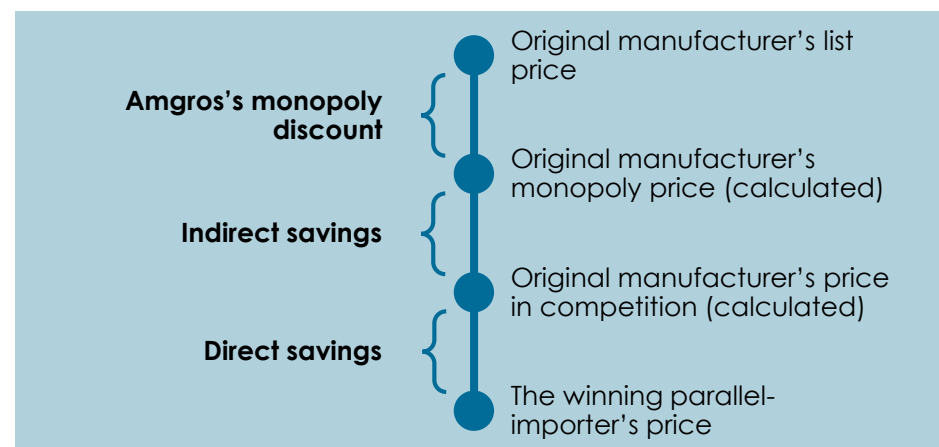
DKK million



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

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

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



Source: Copenhagen Economics

Regulation in the hospital sector limits the extent of 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. For this reason, among others, the parallel importers' market share in the hospital sector in 2018 was only 7%, corresponding to DKK 0.9 billion.

Prices are set through tenders with one-year contracts

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

Amgro's framework contracts typically apply for one year, but with the option to extend for one additional year without a new tender.

Amgro carries out tenders and establishes 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 a risk in the form of a supply obligation

Suppliers of pharmaceuticals to Amgro assume an obligation to supply which triggers a financial cost in the event of breach. It can be difficult for parallel importers to ensure supplies of pharmaceuticals up front for a full year and at a specified price. The one-year periods with a supply obligation make the hospital sector less attractive for parallel importers compared to the primary care sector. This can, in turn, mean that some parallel importers do not participate in Amgro's 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 Amgro for the additional cost of 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 the volume of medicines they will be able to purchase 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 Amgro's 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 a stronger incentive to set a low price. However, the longer contracts and stricter supply obligations also mean that fewer suppliers place bids in the tenders. If the loser of a tender fully withdraws from the market, it may limit competition for contracts between tenders.

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.

Increasing expenditure on pharmaceuticals in the hospital sector

The expenditure on hospital pharmaceuticals rose by almost 50% between 2014 and 2018, to DKK 12 billion; see Figure 2. In the same period, expenditure on primary sector pharmaceuticals rose by less than 5%. This means that the hospital sector drives the current increases in the expenditure on pharmaceuticals. It is also in the hospital sector that parallel import of pharmaceuticals has a relatively small market share.

4 METHODOLOGY



Methodology



As a basis for this analysis, we conducted a literature review and background interviews with six experts and researchers in health economics, shown in Table 2. In addition to the six interviewees, listed in the table, we also invited Professor P. Kanavos (see slide 9) from the London School of Economics to be interviewed, but he did not respond to our enquiries. In addition, we discussed specific interpretations and legislation as well as the current regulation with public authorities.

Subsequently, we conducted data analytics in order to calculate the direct and indirect savings obtained from parallel import of pharmaceuticals in the primary care and hospital sectors.

Comparison between factual and counterfactual expenditure on pharmaceuticals

In the analysis, we calculate the savings made from parallel imports in Denmark in 2018.

We do this by comparing the actual expenditure with the counterfactual expenditure that would have been incurred in the absence of parallel imports, quantifying both direct and indirect savings.

We have calculated the direct savings by comparing the actual expenditure 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 calculated prices the original manufacturers would have bid 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 three slides show the methodology employed in the primary care and hospital sectors in more detail.

Table 2. Interviewees

Name	Title	Organisation
Anders Munk-Nielsen	Tenure Track Assistant Professor	University of Copenhagen
Frederik Plum Hauschultz	PhD student	University of Copenhagen
Jakob Kjellberg	Professor	The Danish Center for Social Science Research
Jes Søgaard	Professor	University of Southern Denmark
Kjeld Møller Pedersen	Professor	University of Southern Denmark
Ulrika Enemark	Associate Professor	Aarhus University

Source: Copenhagen Economics

Methodology employed in the primary care sector



Primary sector pharmaceuticals are organised into substitution groups

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 parallel importers' equivalent product.

The organisation of the products into substitution groups allows us to match the original manufacturers and the parallel importers, which is crucial for our calculation. In our data set, each product has an item number and a substitution group number.

Contents of the data set

We have received the data set we base our calculations on from the Danish Association of Parallel Importers of Pharmaceuticals. The data set contains data on turnover, volumes and prices for each of the 27 tenders in 2018, calculated partly per substitution group and partly per item number.

Data cleaning

Our results are based on data from 618 substitution groups. We went through the following data cleaning steps to end up with this data set:

We start with a data set with 1,768 observations (i.e. substitution groups).

- We delete observations that lack a parallel importer or original manufacturer
- We delete observations with incorrect data, e.g.

where parallel imports and generics are listed as being from the original manufacturer

- We delete substitution groups with more than one original manufacturer, or where the number of original manufacturers is unknown (N/A)
- We delete observations with missing price data, volumes or item numbers.

The elimination of substitution groups with more than one original manufacturer, e.g. in the case of generic competition, means that we only include savings if they are solely attributable to parallel imports, which contributes to making the results conservative.

Direct and indirect savings

To calculate the savings that parallel import of pharmaceuticals gave rise to in the primary care sector in 2018, we compare the total expenditure on the parallel-imported primary sector pharmaceuticals in Denmark in 2018 with the expenditure that would have been incurred in a situation without parallel importers. In other words, we assume that the same volumes would have been sold at the original manufacturers' prices.

$$\text{savings} = e_{\text{counterfactual}} - e_{\text{factual}}$$
$$= (v_{DI} + v_{PI}) * p_{DI} - (p_{PI} * v_{PI} + p_{DI} * v_{DI})$$

with e = expenditure, v = volume sold, p = price per unit, PI = parallel import and DI = original manufacturer.

To calculate the *direct savings*, we compare the factual expenditure and the expenditure that would have been incurred if the same volume of pharmaceuticals had been sold at the original manufacturers' factual prices, i.e. the prices the original manufacturer placed in bids in the 27 tenders in 2018 while there was competition from

parallel importers.

$$\text{direct savings} = (v_{DI} + v_{PI}) * p_{DI, \text{with competition}} - (p_{PI} * v_{PI} + p_{DI} * v_{DI})$$

To obtain the *indirect savings*, we compare the factual expenditure with the expenditure that would have been incurred if the same volume of pharmaceuticals had been sold at the original manufacturers' monopoly prices. We do not know the monopoly prices and therefore have to estimate them; see next slide.

$$\text{total savings} = (v_{DI} + v_{PI}) * p_{DI, \text{monopoly}} - (p_{PI} * v_{PI} + p_{DI} * v_{DI})$$

Tenders in which the original manufacturer did not bid

There are some tenders for individual products in which the original manufacturer did not place a bid, e.g. due to supply problems. We have removed these tenders (only the tenders, not entire products) from the calculation of both the factual and counterfactual expenditure. The reason for this is that we would otherwise underestimate the savings. Missing bids are accounted for in the data with $p_{DI} = 0$, which means that the counterfactual expenditure $(v_{DI} + v_{PI}) * p_{DI}$ is also zero. If there is a positive factual expenditure in the tenders' contractual periods, i.e. if parallel-imported pharmaceuticals are sold, the savings are shown as negative. However, this situation does not correspond to an economic loss, and we have therefore set the savings to zero instead of negative values in these tenders.

We have not removed tenders that lack bids from parallel importers, as they do not result in a bias in the savings. In these cases, where only the original manufacturer's pharmaceuticals are sold, the actual expenditure correspond to the counterfactual ones, and the savings are zero.

Methodology employed in the primary care sector



Calculation of monopoly prices

In order to calculate the indirect savings, we need the original manufacturers' monopoly prices, i.e. the prices they would have set if there was no competition. These prices are unknown, which means that we need to calculate them.

We have chosen the highest average price that the original manufacturers placed as bids over a full year from 2014 to 2018 as the monopoly price. See Figure 12. This means that we take a moving average across 27 tenders and select the highest of these average prices. It is a conservative estimate of the monopoly

price – you could also argue in favour of using a shorter time period, i.e. fewer tenders. For example, if we use a moving average across 13, 7 or 3 tenders instead of 27, the indirect savings would be higher, i.e. DKK 352 million, DKK 370 million and DKK 382 million, respectively, instead of DKK 319 million.

By using the highest average over a period of a full year, we ensure that possible outliers in the data do not define the monopoly price, and that we do not overestimate the indirect savings. In other words, our estimate is based on a conservative approach.

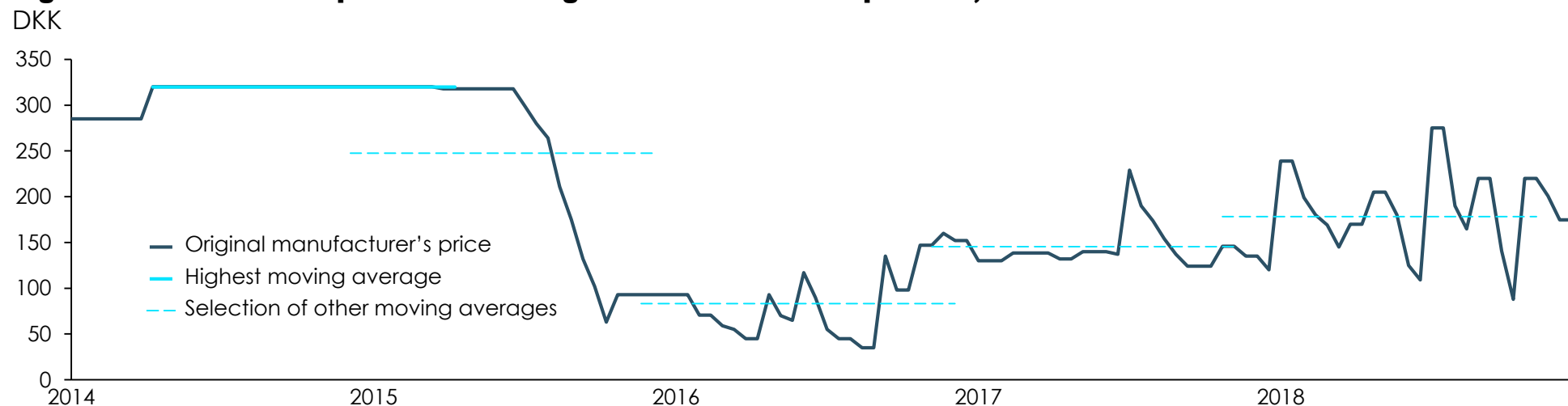
It is worth noting that, overall, the prices for the primary sector pharmaceuticals do not show a downward trend between 2014 and 2018.

Assumptions

Our calculation is based on the following assumptions:

- Inelastic demand for pharmaceuticals. We assume that the same volumes would have been sold at the original manufacturer's prices.
- We assume an average price for parallel-imported products in the tenders we remove due to a missing bid of the original manufacturer.

Figure 12. Price development for an original manufacturer's product, 2014-2018



Source: Copenhagen Economics, based on Danish Drug Information

Methodology employed in the secondary care sector



Savings

To calculate the savings from parallel imports of pharmaceuticals in the hospital sector in 2018, we compare the total expenditure on parallel-imported pharmaceuticals in the Danish hospital sector in 2018 with the expenditure that would have been incurred if the same volume of pharmaceuticals had been sold at the original manufacturers' prices. In other words, we compare the factual expenditure with a counterfactual expenditure, where the volumes are unchanged, but the prices are changed to the original manufacturers' prices for all the products sold.

$$\begin{aligned} \text{savings} &= e_{\text{counterfactual}} - e_{\text{factual}} \\ &= (v_{DI} + v_{PI}) * p_{DI} - (p_{PI} * v_{PI} + p_{DI} * v_{DI}) \end{aligned}$$

with e = expenditure, v = volume sold, p = price per unit, PI = parallel importer and DI = the original manufacturer.

Hospital sector pharmaceuticals are organised into substitution groups

Virtually all the pharmaceuticals that are dispensed in Danish public hospitals are purchased through Amgro. Amgro typically carries out tenders with one-year contracts, and most of the contracts in our data set cover the period 1 April 2018 to 31 March 2019.

Due to the voluntary price agreements between the Danish Ministry of Health, the Danish Association of the Pharmaceutical Industry and the Danish Regions, a number of original manufacturers have

reduced their prices systematically, especially in February 2019, which we have taken into account in our calculations.

Contents of the data set

We have received data sets for four parallel importers, including 2care4, Abacus Medicine and Orifarm. The data sets contain the parallel importers' prices and volumes sold, as well as the original manufacturers' list prices. Our results are calculated on the basis of data on more than 100 different item numbers.

Calculation of the counterfactual expenditure

By multiplying the volumes sold at both the parallel importers' and original manufacturers' prices, we find the factual and counterfactual expenditure on pharmaceuticals (i.e. if the original manufacturers had sold the entire volume at their own prices in the absence of competition). When we subtract the average discounts that Amgro obtains from the original manufacturers in different competitive settings, the remaining difference constitutes the savings from parallel imports.

Amgro's discounts

When it comes to the original manufacturers' list prices, Amgro obtains the following discounts on hospital pharmaceuticals¹:

- Monopoly: 14.6%
- Limited competition: 21.6%

Assumptions

Our calculation is based on the following

assumptions:

- Since we lack data for a number of products for March 2019, we have assumed and used the average prices and volumes in the previous 11 months – between 1 April 2018 and 28 February 2019 – to estimate prices and volumes for March 2019.
- We have only included savings if the original manufacturer has been active on the market. In other words, we assume the savings are zero when the parallel importer is alone in the market. If the buyer had purchased the products in question outside Denmark, the price might have been higher than the monopoly price or even the original manufacturer's list price. Therefore, this assumption contributes to underestimating the savings obtained from parallel imports.
- Amgro's 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. Whereas the monopoly discount determines the size of the total savings derived from parallel imports, the limited competition discount determines the relation between direct and indirect savings.

Dynamic effects only influence the results on savings marginally



In this analysis, we calculate savings derived from parallel import of pharmaceuticals in Denmark in 2018. For this purpose, we have assumed an inelastic demand for pharmaceuticals, and that the parallel import's 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 volume 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 also here 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 2018. For the same reason, it would be much more complex to compare 2018 with a counterfactual scenario in which both the prices and traded volumes were changed.

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' possibilities of price discriminating across the 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 are sufficiently widespread 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 regarding launch and pricing of pharmaceuticals in the EU/EEA countries where the parallel importers source products to be sold in Denmark. If the original manufacturers know which countries the parallel importers source their products from, 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 a launch or not to launch a product at all in countries where the parallel importers source their products, in order to prevent parallel imports.

Denmark makes up a very small share of the global market for pharmaceuticals. This means that lower turnover in Denmark has little influence on an original manufacturer's overall earnings. Moreover, 2018 has ended which means the savings have already been realised. Therefore, parallel imports of pharmaceuticals in Denmark in 2018 only gave original manufacturers a very small incentive to change their behaviour as described above.

If this analysis were to be repeated at a European or global scale, 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.

THE EFFECT OF PARALLEL-IMPORTED PHARMACEUTICALS

An assessment of savings in Denmark

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Copenhagen Economics is one of the leading economics firms in Europe. Founded in 2000, we currently employ more than 90 staff operating from our offices in Copenhagen, Stockholm, Helsinki, and Brussels. The 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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