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SAVINGS FROM PARALLEL IMPORTS IN EUROPE

A review of the recent studies

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Title: Savings from parallel imports in Europe

Authors: Esco Aguiar, Kasper Ernest


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Publisher: Affordable Medicines Europe

 Rue des Deux Eglises 26, 1000 Brussels

 info@affordablemedicines.eu

 +32 491 255 611

 www.affordablemedicines.eu

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FOREWORD

This year, 2020, marks the change of the name from EAEPC (European Association of Euro-Pharmaceutical Companies) to Affordable Medicines Europe. The new name highlights the fundamental purpose of the companies we represent: to offer a better deal for the supply of European original medicines. Parallel imports of pharmaceuticals provides social benefits to European countries by challenging monopolies to create savings for public health systems.

The continuous increase of the health budgets across the continent has become a central issue in the political debate. Expenditure on pharmaceuticals and medical services represents a growingly larger share of national budgets. In this climate, governments and European institutions are looking at potential gains for efficiency and sustainability of health systems.

This challenge has spurred many attempts to rein in medicines prices in EU. Secret price negotiations have been a route many governments have taken, despite the toll they have on transparency. Recently, buying alliances such as Beneluxa and the Valletta Declaration have been established as a cooperative measure to restrict expenditure on medicines.

However, it is difficult to reduce the negotiation power of pharmaceutical companies in a quasi-monopolistic market. For four decades straight, parallel imports have been the main source of competition for patented pharmaceuticals. Although its scope is limited, it has helped to contain and reduce medicine prices bringing sizable savings to European governments and pharmacies.

This review of the recent studies on savings provides sound evidence about the significant benefits of parallel imports in four different countries. The benefits are translated into reliefs of national health budgets or/and better profitability for pharmacies. Of course, savings are greater in those countries with appropriate frameworks for parallel imports.

The parallel trade turnover is constant around €5.5 billion at the EU level, but its proportion in relation to the market of pharmaceuticals decreases every year as general expenditure on medicines is on the rise. Now it represents be-



Kasper Ernest

Secretary General

Affordable Medicines Europe

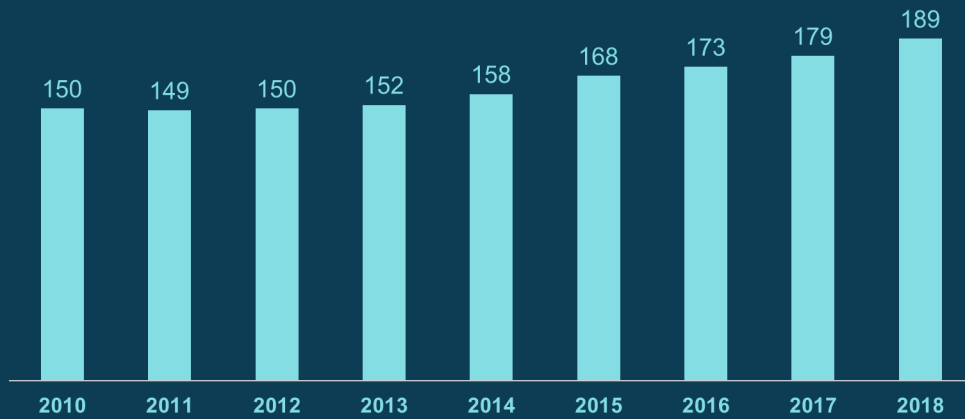
low 3% of the total sale of medicines. This means savings would be far greater today if parallel trade had been allowed to develop at the same rate as the general medicines market.

There is potential for all European countries to benefit from trade, should the remaining regulatory hurdles be removed both for parallel import and export of pharmaceuticals. The flows of parallel trade go in many directions, and every country can find opportunities to take advantage of lower prices. National governments and EU institutions should promote competition in the market and create favourable frameworks for parallel trade of medicines.

Affordable Medicines Europe will use the results of these studies to prove to policymakers and stakeholders the positive effects of promoting competition in the pharmaceuticals market, as well as the key role of parallel imports in containing health budgets in Europe.

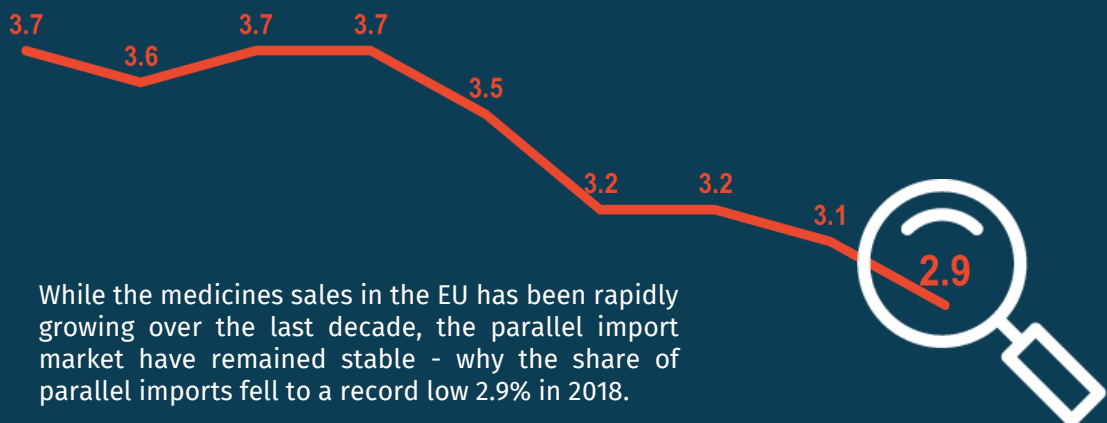
Kasper Ernest
Secretary General

Turnover EU medicines market in billion €



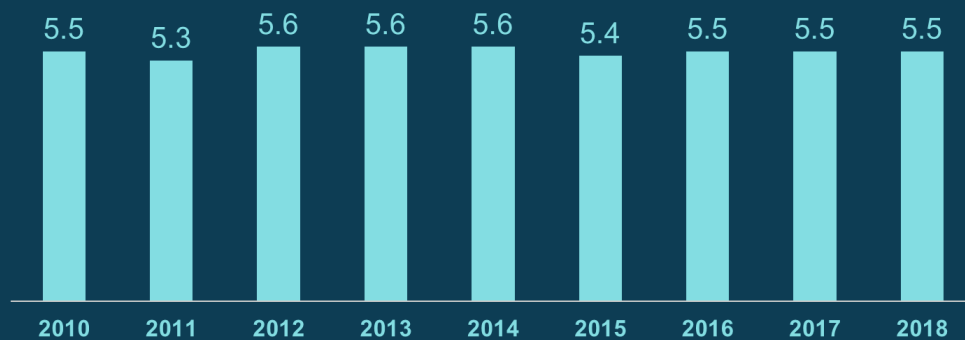
Source: EFPIA

Share of the total market in %



While the medicines sales in the EU has been rapidly growing over the last decade, the parallel import market have remained stable - why the share of parallel imports fell to a record low 2.9% in 2018.

Turnover of EU parallel import in billion €



Source: IQVIA



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EXECUTIVE SUMMARY

Recent economic studies continue to demonstrate the existence of significant savings from parallel imports in countries like **Germany, Sweden, Denmark** and **Poland**. These savings come from both the price differential between the original manufacturer's medicine and the parallel import equivalent; and from the competitive pressure exerted on prices by the parallel import when they enter the market.

Parallel imports brings more affordable medicines to European patients with the same high standards of quality and safety. Parallel imports are the only competition to pharmaceuticals that are still under patent protection, and they help to contain the growing health budgets in Europe.

The total amount of savings in these four markets adds up to €3.2 billion in 2018. The indirect savings, i.e. those coming from the PI competition, are considerably larger than the savings that are originated from the price difference between the originator and the parallel imported medicine, i.e. direct savings. For Sweden and Germany, the savings figures account for those of the pharmacy market alone, while for Denmark and Poland they also include the parallel imports supplied to hospitals.



- Direct savings = €360 million
- Indirect savings = €2,883 million



€2,802 million savings

€202 million in direct savings
€2.6 billion in indirect savings



€235 million savings

€60 million in direct savings
€175 million in indirect savings



€82 million savings

€31 million in direct savings
€51 million in indirect savings



€124 million savings

€67 million in direct savings
€57 million in indirect savings

Although these savings are already significant, the regulatory framework and remaining barriers to both parallel imports and exports are hindering the potential for even larger savings. While this review focuses on four countries, all EU Member States are able to enjoy savings provided they create the right incentives to dispense less costly parallel imports. However, in order to obtain these, it is key to promote the purchase of the most affordable option and remove the unjustified hurdles to trade of medicines in Europe. **National governments and European institutions should foster more competition in the pharmaceutical market.**

WHAT IS PARALLEL IMPORT?



Parallel import is an integral part of the medicines supply chain in the Single Market. Trade in medicines is not only legal but also strictly regulated under EU and national regulation. Parallel import requires both GDP and GMP licenses as well as import authorisations. Parallel imports are also subject to the requirements of the Falsified Medicines Directive.



Parallel import in the Single Market is protected by the principle of exhaustion of Intellectual Property (IP) rights. The exhaustion principle prevents rights owners from restricting further distribution of their products once they have placed these on a given EEA market. That is because the IP owners have already extracted their 'ownership profit' with the first sale in the Single Market. This right cannot be used to obtain a double profit from IP by fragmentation of the Single Market.



Parallel import helps prevent price compartmentalisation of national markets. It uses the price differences in European Economic Area (EEA) to bring savings for national health systems and pharmacies. Savings from parallel trade are twofold; direct savings by selling at a lower price than the originator, and indirect savings coming from the reduction of the price of originators' medicines due to competition introduced by parallel imports.



INTRODUCTION

Parallel imports bring original European medicines from one Member State of the EU/EEA to another at a lower price with the same high standards of quality and safety. Health systems, pharmacies and, ultimately, patients reap the benefits of the price difference between the medicine put in the market by the manufacturers and the lower-priced import brought by parallel distributors.

Parallel imported medicines are the main source of competition for patented medicines. Pharmaceutical companies enjoy extensive protection under EU patent law. While it is important to safeguard the feasibility of research to ensure continued innovation – medicines are essential for patients' livelihood, and therefore the price inelasticity (low price sensitivity on the demand side) is the rule. This allows for the potential of right owners exploiting their innovations beyond what is fair.

Government expenditure on healthcare has been growing over the last decade. Parallel imports bring sizable savings that help to contain the constantly increasing healthcare budgets.

Health authorities, regulators and relevant actors in the healthcare system have promoted the benefits of parallel trade, as well as its positive effects on competition and reducing the costs of the medicines. In April 2019, the German health insurances association defended the import promotion clause for pharmaceuticals, as the parallel import of pharmaceuticals has become an "effective instrument for economic supply of medicines" (Verband der Ersatzkassen, 2019). The European Commission also took a stance against the restrictions to parallel trade in its recent report about competition enforcement in the pharmaceutical sector (European Commission, 2019).

Pharmaceutical companies have consistently tried to undermine the benefits of parallel trade. However, a number of studies have quantified the savings in Europe. The estimations of their amount are far from negligible.

This report provides a general overview of the relationship between parallel imports and savings for the healthcare system; a brief look at the previous studies on the topic; and a compi-

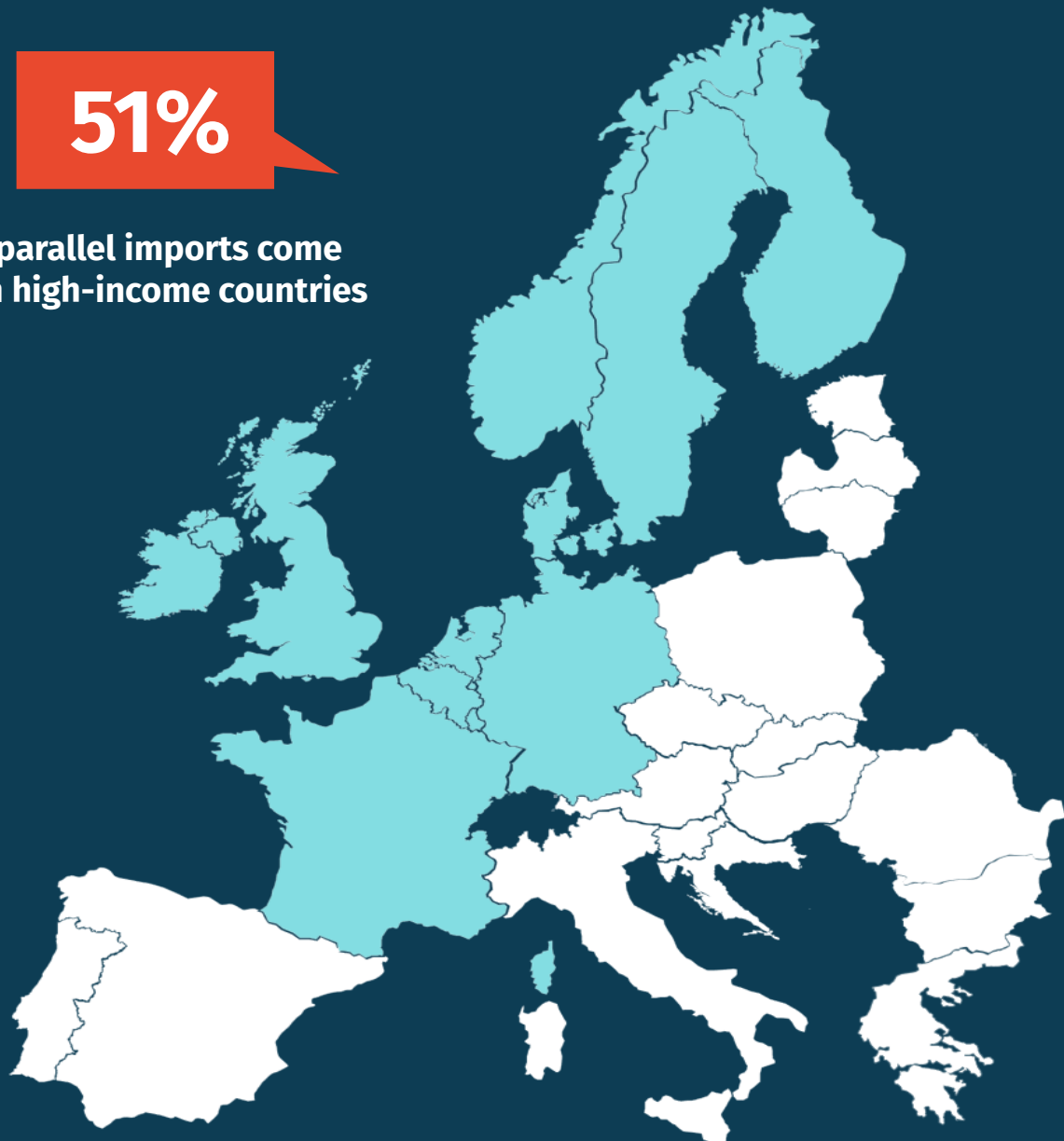
lation of the findings of the most recent studies on savings that have been published between 2018 and 2019. These were conducted by external research entities for Poland, Germany, Sweden and Denmark:

- NERA Economic Consulting calculated indirect savings as a proportion of the originators' revenue for Germany and Sweden. These savings were extrapolated for the whole relevant market by Inno AG and Affordable Medicines Europe respectively.
- Prognos AG calculated the potential and realised direct savings in Germany for the last four years. The direct savings in Sweden are based on the estimation of the Swedish drugs agency, TLV.
- Copenhagen Economics elaborated a report that analyses and quantifies the direct and indirect savings coming from parallel imports in Denmark.
- The Association of Importers of Parallel Medicinal Products (SIRPL) commissioned a report (audited by Deloitte) that calculated the direct and indirect savings in Poland.

All the studies referred to in this report are available on www.affordablemedicines.eu.

51%

**of parallel imports come
from high-income countries**



Definition of high-income countries



We consider high-income the twelve countries with the highest GDP per capita in 2018 in the EU according to Eurostat plus Norway, which also has a relevant PI market. These are: Luxembourg, Norway, Ireland, Denmark, Sweden, Netherlands, Austria, Finland, Germany, Belgium, France, and the UK.



SAVINGS FROM PARALLEL IMPORTS

Parallel imports bring more affordable medicines to patients and foster competition in the European pharmaceutical markets. The following sections will explain which the sources of the savings from parallel imports are, the different types of savings and how they can be found in exporting countries thanks to the ERP system.

Price differences and identification of opportunities

Pricing of pharmaceuticals is a national competence, and significant variations arise across countries in Europe. In some Member States, like Sweden, a national reimbursement price is set by the national drugs agency, so manufacturers and parallel importers will set their prices taking this as a reference. In others, like Denmark, manufacturers and parallel importers alike are free to set the price, but the reimbursement is calculated on the basis of the least costly option in a fifteen days tender.

EU countries present different national regulatory environments, diverse degree of monopolistic power on the supply side and unequal price-setting responses to exchange rate variations. As a result, price differences across countries arise in the European Economic Area. There might be significant disparities in the price of the same original medicine commercialised by the manufacturer in two countries. Parallel importers must identify these opportunities to bring more affordable pharmaceuticals into the market and be able to compete with the originators.

However, the mere existence of a price differential for a certain medicine is not enough for parallel trade to occur. Parallel importers face costs related with purchasing, regulatory compliance, transport, warehousing, insurance, repackaging, quality assurance, trade and promotion. Only if after all these additional expenses the parallel imported product is expected to be sold at a lower price than the manufacturer's, the transaction will take place.

Contrary to common belief, a lower price level of the medicines in a certain country is not indicative of the absence of opportunities for parallel import. The same applies to exports: the

prices of pharmaceuticals within the same country are not completely homogenous, and, very often, opportunities for export can be identified even when the general price level of the medicines is relatively higher than other countries'.

Evidence has shown that more than half of the parallel imports are sourced in high-income countries. France and UK are the main sources of PI in the European Economic Area in 2018, and Germany is in the top three main sources of imports for 9 out of the 14 countries analysed in an upcoming Affordable Medicines Europe study¹.

Direct and indirect savings

Parallel imports of medicines produce savings that benefit national health systems, pharmacists and patients. The distribution of these benefits depends on the legislative framework of the country and the reimbursement systems. While in some countries benefits are reaped by the healthcare system, in other the pharmacies are the ones that keep the price difference and, therefore, the extra revenue.

The savings that stem from the price differential between the parallel import and the identical medicines sold by the manufacturer in the country at a higher price are called **direct savings**. These are easier to quantify, as it is enough to identify this price difference and multiply it for the number of parallel imported packs sold in a given time period.

The **indirect savings** are generated from the competitive pressure that the parallel imports exert on the market. In other words, the price of the medicine marketed by the manufacturer will tend to decrease when it faces the competition of the more affordable parallel imports, creating savings. In addition to this effect, there is also an indirect saving that can be originated by the potential competitive pressure. This happens when the manufacturer decides to lower the price to prevent the entry of parallel imported medicines into the market.

Although the indirect savings are as relevant as the direct savings, and often larger in value, they are more difficult to calculate because there is no precise method to determine the price of the manufacturers in the absence of competition (counterfactual price) once the parallel imported medicine is in the market. However, this counterfactual price can still be estimated. Three different approaches in the calculation of the indirect savings for Poland, Germany, Sweden and Denmark will be presented in this report.

Unlocking the potential for more savings from parallel import

Savings could be greater at the European level if the remaining obstacles to parallel trade were finally eliminated. Many countries lack proper frameworks for both imports and exports, and there are still some restrictions to parallel trade that are not proportional according to what is established in the EU Treaties.

Concerning the imports, some Member States have a different reimbursement policy for parallel imported medicines, that puts them at a disadvantageous position with respect to the equivalent product commercialised by the manufacturer. In other countries, extra administrative burden hampers the entry of parallel imports into the market.

Regarding the exports, a number of countries

have unproportionate restrictions in place that limit or prohibit the trade of medicines. While controlling the exports of medicines at shortage are justified, the criteria for these medicines to be banned from trade should be clear, proportionate and consistent. Export restrictions should respond to actual shortages, when there is no generic or alternative treatment available, and be removed once the problem is solved.

If the restrictions to parallel trade were always justified and properly implemented, no countries would experience negative effects of exports, while all countries could experience the benefits of imports. This is the healthy parallel trade eco-system we advocate to achieve.

Pharmaceutical companies not only have a privileged position in the price setting of medicines, they also fragment the internal market to obtain the highest possible prices in each Member State. Price discrimination allows them to extract the maximum profit of each country based on their ability to pay for medicines or their negotiation power.

While on average prices tend to be lower in low-income countries, for a large range of products this is not the case. In fact, parallel distributors frequently buy the same medicine at a low price in a high-income country (e.g. Germany) and import it to a low-income country (e.g. Lithuania) where the price is otherwise higher.

Rather than ensuring that the Internal Market delivers the best price to patients all over Eu-

Savings do not reflect the profit of the parallel traders

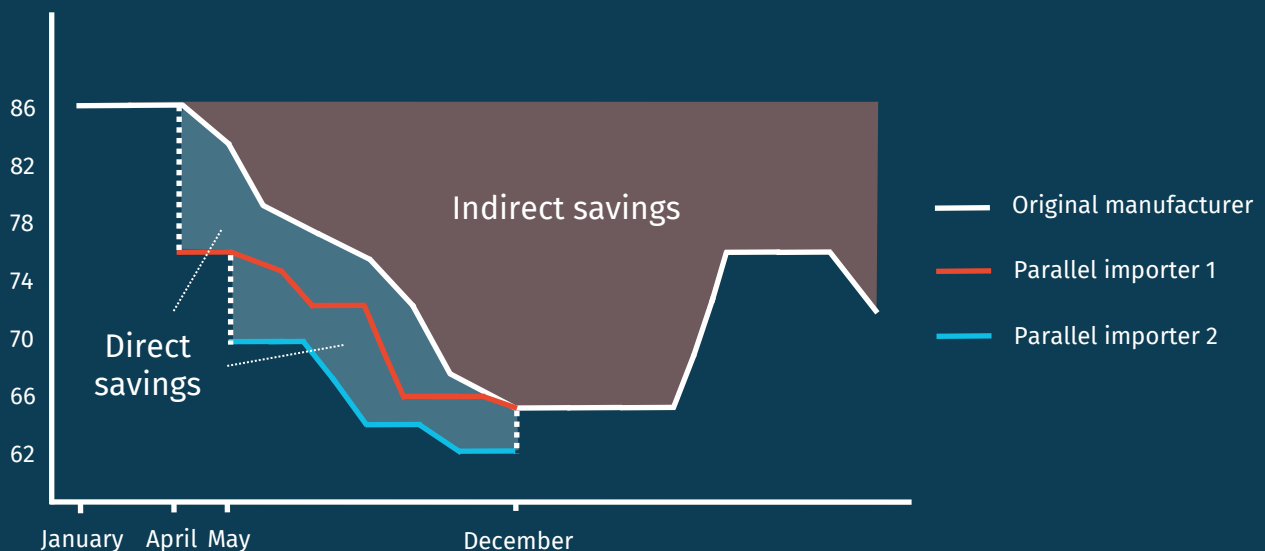
There is a common misconception that is often used by stakeholders to attack parallel trade of pharmaceuticals: parallel imports do not generate savings, but only profits for the parallel traders. This statement is completely incorrect, as the calculation of the savings is elaborated with retail prices of pharmaceuticals. Therefore, the profit of the parallel traders is not considered as part of the savings.

As it has been explained throughout this publication, the distribution of the savings depends on how the health care system is configured and how the pricing mechanisms work in each country. In most countries, savings are reaped by the government, public health insurers or pharmacies.



Direct and indirect savings: a visual approach

The difference between direct and indirect savings can be easily explained with a graphical representation of an example: a medicine is released in the market of country A in January 2010 at 86€. In April, parallel importer 1 brings the same medicine to country A from country B at a lower price: 76€. One month after, another parallel importer brings the same medicine, this time from country C, at 70€.



The market is not static, and each agent reacts to the price set by the others. Therefore, the originator lowers the price to face the competition of more affordable parallel imported alternatives. Many months later, in December, the originator sets the price at a level that is not sustainable for the parallel importer to remain in the market.

The area coloured in light blue represents the direct savings, i.e. the difference between the price set by the originator and the parallel importers. The upper area coloured in light pink represents the indirect savings, that stem from the reduction of the originator's price due the competition pressure exerted by parallel importers.

The introduction of imports have brought substantial competition and savings. Once parallel importers have invested in a license, they can enter the market with weeks notice should the manufacturer again raise its prices.

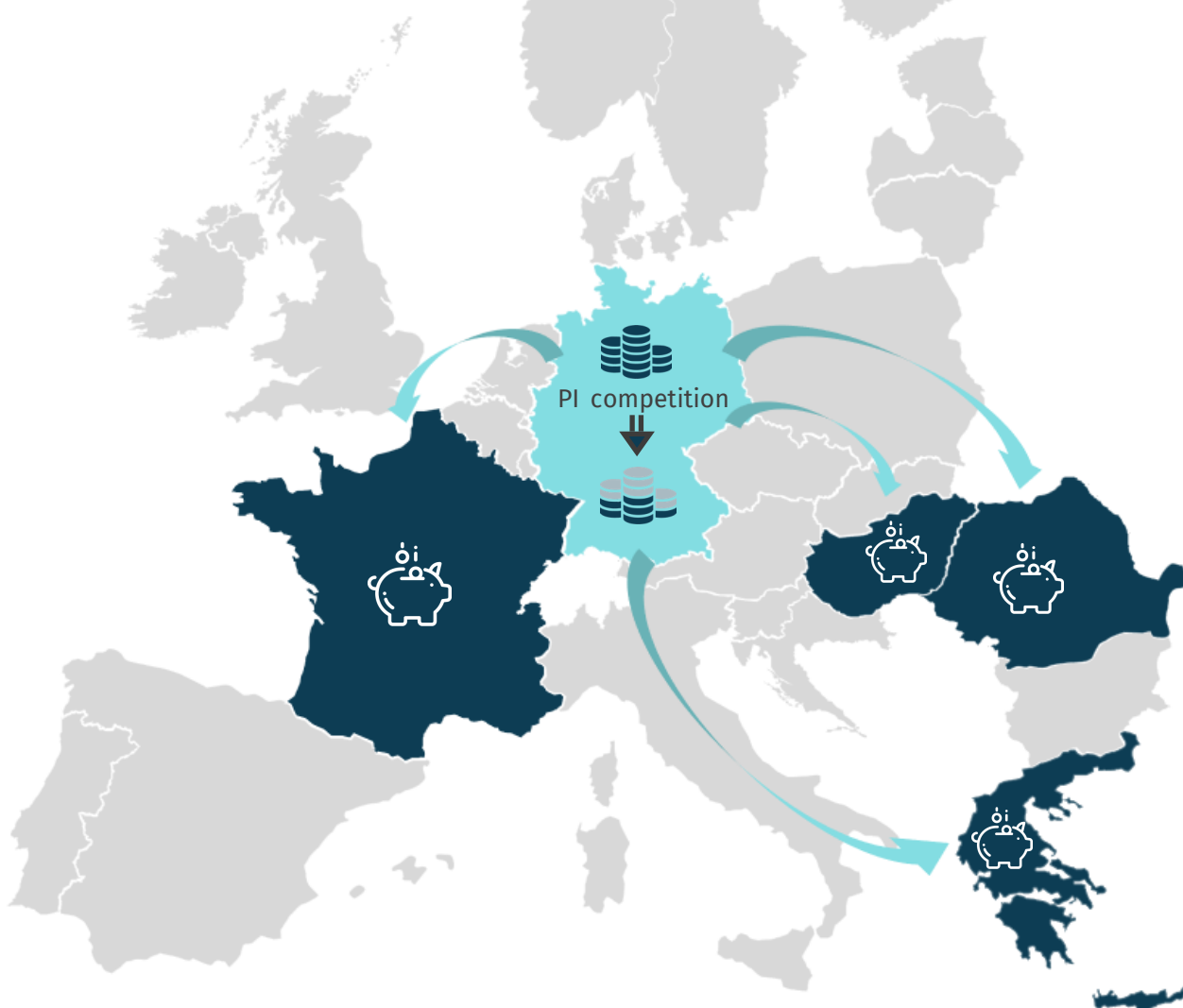
rope, patients suffer from what is effectively geo-blocking of medicines. Parallel imports are the only means policymakers currently have to negate the effects of these constraints.

Savings in exporting countries via the ERP

Most countries in the EU/EEA use the External Reference Price criteria (ERP) in their pricing system of pharmaceutical products, either as the main criteria or as a supportive one. The ERP takes into consideration the prices a basket of countries (normally, other EEA countries in the case of Europe) before setting (or when evaluating) the price of a certain medicine. The

composition of the baskets and the application of the ERP differs significantly among countries. In some cases, the price has to be equal to the lowest price available in the reference countries; in others it is an average of the three or four lowest prices.

The fact that ERP criteria used in most pricing systems consequently means that, with the effect of parallel imports lowering prices in one country, price reductions are also 'transferred' to other countries. This includes countries with no or very little imports. In other words, price competition from parallel imports provoke a domino effect reducing the prices in those countries taking them as reference.



When the price in importing country decreases due to the competition from PI, it creates savings in the countries that have it as a reference in their basket.



ANALYSIS OF THE SAVINGS



OVERVIEW OF THE MAIN RESULTS

In total, the savings from parallel imports calculated for Germany, Sweden, Denmark and Poland add up to approximately €3.2 billion in 2018. Sizeable savings were found in the three countries, which represent a significant amount of the total spending in pharmaceuticals.

Europe for parallel imports by a considerable margin. Not only the legislative and regulatory framework are favourable for the entry of PI, but also the population and the number of patients cannot be compared with the other countries in this summary. In relative terms, total savings

Savings in EUR million	Direct savings	Indirect savings	Total savings
Germany	202	2,600	2,802
Sweden	60 ¹	175	235
Denmark	31	51	82
Poland	67 ²	57	124
Total	360	2,883	3,243

Direct saving amounted to €202 million in Germany, €60 million in Sweden, €31 million euro in Denmark and €67 million in Poland; while the indirect savings added up to 57, 2600, 175 and 51 million euro respectively.

These savings figures need to be put into perspective. The German is the largest market in

account for 6% of the total expenditure in medicines for pharmacies in Germany, 6% in Sweden, 3% in Denmark and 1.8% in Poland.

Also, as a percentage of the originators' revenues for the import relevant market, total savings in the pharmacy sector represent a similar share: 18% in Germany, 16.5% in Sweden, 22% in Denmark and 15% in Poland.

Savings	% of total cost of pharmaceuticals
Germany	5.8%
Sweden	6.3%
Denmark	3.0%
Poland	1.8%

Savings	% of originators' revenue
Germany	18%
Sweden	17%
Denmark	22%
Poland	15%

¹ The Polish direct savings include the ones of the patients and the National Health Fund.

² Savings for Sweden are the median of the lower and higher bounds (€50-€70 million) of the estimation elaborated by the Swedish Drugs Agency TLV for 2017. More information on the correspondent section.

The potential for savings in Denmark is also capped how the specialties market is distributed between pharmacies and hospitals. These medicines normally have a higher price and

greater price differences with other countries, which means more savings from parallel imports. The share of specialties sold in pharmacies in Denmark is almost negligible, while most of them are provided in hospitals. Both in Sweden and Germany, the majority of the specialties are sold

in pharmacies. In Poland, parallel imports alternatives to the branded medicines are treated as generics, even when they are not, which hinders the competition in the pharmaceutical sector of the country.



THERE IS SCOPE FOR LARGER SAVINGS

The diverse methodologies used in the studies summarised in this report are rather conservative, and they tend to underestimate the real amount of savings. Regarding the indirect savings, none of the studies is able to capture the savings coming from the potential competition from parallel imports. In other words, the manufacturers are incentivised to set a price sufficiently low to dissuade the entry of parallel imports into the market. In absence of the threat of competition from parallel import, manufacturers would probably set a higher price.

In addition to this, the savings for Germany and Sweden only include those that are originated in pharmacy sales of parallel imports. Therefore, the savings stemming from the purchase of parallel imported medicines by hospitals are not considered in the calculations. As a consequence, the results underestimate the real amount of savings in these countries.

On the other hand, regulatory barriers limit the achievement of greater savings. For instance, in Germany, the incentive to dispense less costly parallel imported pharmaceuticals only affects to 5% of the total volume per insurance fund. If this incentive was always applied, the potential savings would be about 50% higher.

In Denmark, the differences in regulation between pharmacies and hospital purchases of pharmaceuticals and the entry barriers for parallel importers cause a big difference in the share of PI over the total pharmaceutical sales: 26% in pharmacies, only 7% in hospitals.



STUDIES OF THE SAVINGS IN GERMANY

Germany is by far the biggest market for parallel imports in terms of sales. In 2018, sales of PI amounted to €2.9 billion, which represents about 8.5% share of the total pharmacy market sales³.

Until July 2019, German pharmacies were obliged to dispense PI medicines when these are 15% or 15 € lower than the price of the reference medicinal product. Until a quota of 5% of the total volume per insurance fund of those lower priced products is fulfilled, according to a contract between the association of pharmacists and the Statutory Insurance Funds⁴.

The economic savings from parallel imports are expected, consequently, to be the biggest in Europe as they were in previous studies. **The following savings studies only capture those coming from the pharmacy sales**, leaving outside from the calculation the medicines dispensed in hospitals.

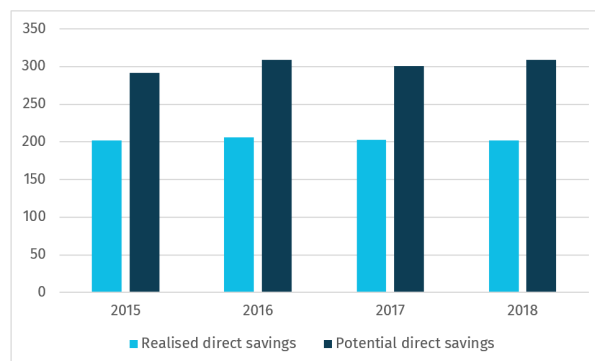
The Swiss economic consulting company **Prognos** conducted in 2018 an analysis of the **direct savings** and the potential direct savings for the German market (Kreuzer, Weinelt, & Johann, 2018). For their research, they used prescription medicines sales and price data from Insight Health for the period January 2015 to October 2018. The focus of the study is limited to reimbursable drugs.

The approach to calculate the savings resembles to the methodology used by Enemark and Pedersen in their studies: they determined the price difference of each drug and its parallel import equivalent and multiply this differential by the volume of PI sales. Savings were calculated for the years 2015-2018, and they ranged between **€202 and €206 million per year** throughout the period. The largest amount of savings was found in the group of medicines that fulfilled the quota, i.e. those with a price difference

at least 15% or 15 euro measured on the reimbursement price of the parallel import and the corresponding original product. About €180 million of the savings came from these products.

The authors of this study consider that the total potential savings volume is even higher, as both pharmacies and consumers have limited incentives to deliver or purchase, respectively, the least costly option if the price difference is less than 15% or 15 euro. These potential savings were estimated to be between €292 and €309 million throughout the period, given that this restriction to the quota was removed.

The calculation of the indirect savings is more complex, as it is necessary to estimate the price



Potential and realised direct savings in Germany. Source: Prognos (2018).

of the originator's medicine if the parallel import had not entered the market when it actually did (the counterfactual price). Therefore, some assumptions are needed.

NERA Economic Consulting undertook this task and approximated the amount of the **indirect savings** as a percentage of the originators' revenues for a subset of products that showed negative correlation between the parallel import share and the originator's price (Posada, 2019). These were the products that experienced a reduction of the price the higher the parallel import market share was.

A range of products did not display the negative correlation, however for this is not unexpected according to NERA. In fact, there are several reasons why this occurs:

³ Data from IQVIA and EFPIA.

⁴ From July 2019, the terms of the agreement have slightly changed, and now the savings quota responds to 2% of the total revenue of the import relevant market. In order to meet this savings target, there must be a price difference of at least 15% when the medicine cost less than €100; €15 when the medicine costs more than €100 but less than €300; and 5% when the medicine costs more than €300.

Savings in EUR million	Direct savings	Indirect savings	Total savings
Pharmacies	202	2,600	2,802
Hospitals	N/A	N/A	-
Total	202	2,600	2,802

- The competitive pressure introduced by the parallel import is reflected in a lower rate at which the originator's price increase, which the methodology cannot capture.
- Manufacturers decide to keep high price not to affect the External Reference price in other countries.
- Manufacturers reduce the effective price using confidential rebate schemes, that are not reflected in the official price of the medicine, and, therefore, these cannot be captured by the available data.

In order to calculate the indirect savings, it was necessary to establish a counterfactual price. NERA's approach relied on the average price of the originator prior to the entry of parallel imports. The indirect savings amounted to 16.7% of originators' revenues for the group that showed a negative correlation. The analysis corresponded to the period 2011-2017.

The author of this study claims these savings are an underestimation of the total indirect savings, as they do take into consideration the "savings that accrue due to the threat of potential market entry of parallel imports, as manufacturers

might reduce prices or engage in rebate agreements to prevent entry from parallel traders in the first place". In other words, the counterfactual price takes into consideration the effects of the actual competition, but not the potential competition. The counterfactual with no threat of parallel imports competition would be even higher, which would result in greater indirect savings. However, the author preferred to opt for the more conservative approach.

The percentage of indirect savings was extrapolated for the parallel import relevant market by **inno AG** (Heydebreck, 2019). In order to obtain the import relevant market, the turnover of the medicines with generic competition and the ones without PI alternative were deducted from the total (about €48 billion in 2018). Then, half of the turnover of medicines under discount agreements was also deducted, using the indifference principle, as "parallel imports lead to indirect savings if the original manufacturers are persuaded to negotiate such discount agreements".

As a result, the PI relevant market amounted to almost €13 billion, and the extrapolated indirect savings added up to **€2.6 billion** in 2018.

Total savings – direct and indirect – **account for 18% of the originators' revenue.**

“ People arguing against the import promotion clause should be able to explain how the arising financial burden on citizens insured by the statutory health Insurance can be avoided. Only a continued actual competition leads to economic efficiency in the supply of pharmaceuticals. ”

Joint press release, 16th April 2019, of the German health insurance associations; vdek, BKK Dachverband, IKK, Knappschaft, and SVLFG.



STUDIES OF THE SAVINGS IN SWEDEN

Sweden is the third biggest market for parallel imports in Europe. Despite its size, significantly smaller than the German, the share of PI is higher in relative terms. In 2018, sales of parallel imported medicines amounted to €400 million, about 13% of the total sales of pharmaceuticals in the country⁵.

In Sweden, the TLV (Dental and Pharmaceutical Benefits Agency) approves the national reimbursement price, that is applicable to both originators' products and parallel importers. Manufacturers and parallel importers have freedom to set the prices of pharmaceutical products, but this will be inevitably linked to the reimbursement price of the Agency's benefit scheme.

Pharmacies are then obliged to dispense the least costly medicine available, including parallel imports as possible substitutes.

Manufacturers and parallel importers are able to negotiate discounts directly with the pharmacy chains. Pharmacies can keep the margin between the official price of reimbursement and the price agreed with the parallel importer. There is no difference in the reimbursement of the parallel imports and the medicines put in the market by the manufacturers or authorised wholesalers.

As in the German case, **the savings only take into consideration the sales in pharmacies** but not the medicines dispensed in hospitals. The market share for parallel imports in the hospital sector was only 3.3% in 2018.

Therefore, the direct savings of the sale of parallel imported pharmaceuticals is retained by the pharmacies in Sweden. Estimates of the agency TLV, based on the data provided by the Swedish pharmacy association, showed direct savings that amounted to SEK 600 million in 2013. Based on this assessment, **TLV's direct savings** estimations for 2017 ranged between **€50 and €70 million per year** (between SEK 500-700 million) (Hortlund, Rönholm, Skiöld, & Stridsberg, 2018).

The savings coming from parallel imported medicines represent almost 20% of the total earnings of the pharmacies in Sweden according to the TLV. The Swedish pharmacy association claims that the benefits from parallel import medicines are crucial for pharmacies' operating profit (Sveriges Apoteksförening, 2017). The incentives to sell parallel imports helped pharmacies in the period of economic crisis, and any negative legal development in this regard would affect significantly to the financial performance of Swedish pharmacies.

The percentage of indirect savings as a proportion of the originators' revenues was calculated by **NERA Economic Consulting** for pharmaceuticals products that showed negative correlation between the parallel imports' market share and the price of the originator between July 2015 and June 2018 (Posada, 2019).

As in the German case, a group of products showed positive correlation or no correlation between these two variables, and it can be explained by similar reasons: even when the originator's medicine price is increasing, parallel imports might prevent even larger increases by their presence in the market; or because the manufacturers prefer not to affect the external reference price in other markets, which might lead to a greater loss of revenue for them in these countries. The methodology cannot capture the competitive effects exerted by parallel imports in these situations.

The counterfactual price chosen for the calculation of the indirect savings was the average price of the originator's medicine prior to the entry of the competing parallel import. This price was then compared with the true observed price for each period.

The indirect savings amounted to 12.3% of the originators' revenue for this group of products. Once again, this approach might be underestimating the actual size of the indirect savings, as it does not take into consideration the savings from the potential competition, i.e. the savings that come from the reductions of the price or the discounts made by the manufacturers to prevent the entry of parallel imports into the market. Once again, the counterfactual price was set in a rather conservative way, as it did

⁵ Data from IQVIA and EFPIA.

Savings in EUR million	Direct savings	Indirect savings	Total savings
Pharmacies	50-70	175.4	225.4-245.4
Hospitals	N/A	N/A	-
Total	50-70	175.4	225.4-245.4

not account for the effect that potential competition from parallel trade might have on the prices before the entry of parallel imports into the market.

The percentage was extrapolated for the whole market following the same methodology that was used for Germany with market data provided by Affordable Medicines Europe's membership. The total prescriptions-only medicines sales in 2018 amounted to €3.8 billion in 2018 (SEK 39.4 billion). Once the sales of medicines with generic competition, the sales of medi-

cines without an import alternative and half of the sales of medicines with a discount agreement are deducted, the remaining import relevant market adds up to €1.4 billion (SEK 14.7 billion).

Therefore, the **indirect savings** extrapolated for the whole import relevant market account for **€175.4 million** (SEK 1.8 billion) in 2018.

If both direct and indirect savings are taking into consideration, total savings account for **17% of the originators' revenue**.



SWEDISH AND GERMAN SAVINGS FIGURES DO NOT INCLUDE PI SALES IN THE HOSPITAL SECTOR

While PI sales represent a significant proportion of the total sales of pharmaceuticals in pharmacies in these two countries, the share of PI distributed in hospitals is considerably smaller, and it has not been taken into account in the calculation of the savings. Hospital savings have been included in the studies of Denmark and Poland.

Parallel importers face more obstacles to distribute their products in hospitals than in pharmacies, which hinders to a great extent the competition in this sector. The procurement systems that regulate the purchase of medicines for hospitals in a number of countries constitute one of the main barriers for the penetration of PI. The contracts normally require a large quantity of products to be supplied for a long period of time (sometimes this exceeds the year). For parallel importers it is very difficult to have the certainty of being able to get sufficient supply to meet the requirements for the whole duration of the contract.

In addition to this, sometimes demands of the contracts related to the production process can only be satisfied by the manufacturers, giving them a *de facto* monopoly for those tenders.

The tender system for hospitals entails a huge risk for parallel importers to participate in this market, which results in less competition and higher prices of pharmaceuticals.



STUDIES OF THE SAVINGS IN DENMARK

The Danish market is also among the largest in the EU, with about €360 million in sales in 2018. It is the biggest market per capita in Europe and it has the largest share of parallel imports over the total pharmacy market sales – about 26% of the total medicines sales in pharmacies⁶.

There is free pricing for medicinal products for pharmacies. In the Danish system, pharmaceutical companies inform the national medicines agency of the price on each product every fifteen days. The Agency informs pharmacies of the prices for each pack in the current price period and pharmacies are then obliged to dispense the least costly option to the patient, unless the patient explicitly wants another more expensive medicine, or the doctor has specifically decided this. The system creates a competitive environment that allows parallel imports to enter the market when they can offer a lower price than the branded equivalent or when this one is in shortage.

The purchase of drugs for the hospital sector is regulated in a different manner. The hospitals' joint wholesaler, Amgros, purchases 99% of the medicines supplied to hospitals through central tenders, where the pharmaceutical companies (including wholesalers) compete to offer the lowest prices and discounts. The market share of PI in hospitals sales is lower than for pharmacies, as it represents 7% of the total sales.

In 2019, the consulting firm **Copenhagen Economics** conducted an analysis of the direct and indirect savings coming from parallel imports in pharmacies and hospitals (Jervelund, Brenøe, & Wilke, 2019).

In the **pharmacy sector**, the total amount of **direct savings** amounted to **€30.4 million** (DKK 226 million) in 2018. Because of the Danish 15-days tender system for medicines for pharmacies, direct savings can be calculated as the difference between the PI winning product and the price offered by the manufacturer in the same tender.

The estimation of the indirect savings was more complex. A dataset of with original producers'

prices in the period 2014-2018 was used in the elaboration of a moving average with a period of one year. The difference between the highest price in the moving average and the actual price at which the original production was sold is interpreted as the response to competition from parallel traders. This approach provided **indirect savings** that amounted to **€43 million** (DKK 319 million) in 2018 for the pharmacy sector.

As stated above, the functioning of the market for pharmaceuticals in hospitals is different and, consequently, the calculation of the direct and indirect savings requires an alternative methodology.

First, manufacturers prices need to be estimated, as they are confidential. Then, an average discount of 14.6% obtained by Amgros is assumed for hospital-reserved monopoly products. The direct savings results from comparing the discount for parallel imports – estimated to be 22.6% – with the original manufacturers' discount for hospital-restricted products under limited competition – 21.6% on average. The remaining difference with the discount offered by manufacturers without competition – 14,6 – represents the indirect savings.

With this methodology, **direct savings for hospitals** amounted to **€1.1 million** (DKK 8 million) and **indirect savings** to **€7.7 million** (DKK 57 million) in 2018.

The total amount of savings, considering both pharmacies and hospitals, direct and indirect savings, add up to €82 million (DKK 610 million) in 2018. These savings represent 3% of the total actual costs of drugs in Denmark; 7% of the total costs of medicines for pharmacies, and 1% of the total costs of medicines for hospitals. Also, **total savings represent 17% of the originators' revenue – 22% in the pharmacy sector, 7% in the hospital sector.**

As the market share is significantly lower, savings are also smaller for the hospital market than for the pharmacy market. The regulatory framework that governs the purchase of medicines for hospitals hampers the development of the parallel imports in this sector. As it was mentioned before, the prices of the medicines

⁶ Data from IQVIA and EFPIA.

Savings in EUR million	Direct savings	Indirect savings	Total savings
Pharmacies	30.4	42.9	73.3
Hospitals	1.1	7.7	8.8
Total	31.5	50.5	82

are set in tenders that normally result in one-year duration contracts with Amgros, with the option to extend it for an additional year without tender.

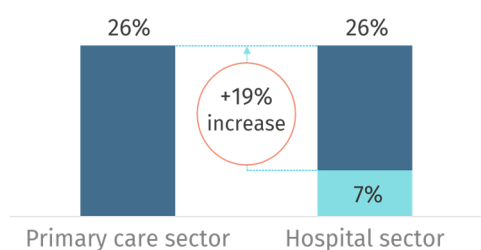
This type of long-term contracts entails a big risk for parallel importers who want to operate in the hospital sector. There is an obligation to supply the medicine at the specified price for the whole duration of the contract. If the parallel importer is not able to supply the product, it will be obliged to compensate Amgros for the cost of purchasing the cheapest alternative to replace it.

Parallel importers are at disadvantage in this situation, as it is not always possible to forecast the volume (and price) of medicines they will be able to get in the following 12 months. This framework hinders competition in the hospital sector, which ultimately results in higher prices for medicines and a rise of public spending.

In the study of Copenhagen Economics there is an analysis of the potential savings if competition was fostered in the purchase of medicine for hospitals, as it is for pharmacies. For this purpose, they calculated the savings in two hypothetical scenarios:

Scenario 1 Additional savings

Parallel importers' market share in the hospital sector rises to 26%

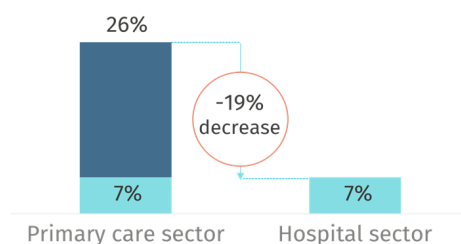


This would lead to an increase of the savings from parallel imports, i.e. a reduction in public spending in medicines of €24 million per year



Scenario 2 Increase of expenditure

Parallel importers' market share in the primary care sector decreases to 7%



This would lead to a reduction of the savings, i.e. an increase of public spending in medicines of €54 million per year



Hypothetical changes of the distribution of the pharmaceutical market for PI and its consequences.
Source: Copenhagen Economics (2019).



STUDIES OF THE SAVINGS IN POLAND

The Polish parallel import market is relatively new and fast growing. It is the main market in Eastern Europe and the sixth largest in Europe. Sales amounted to €100 million in 2018, which represent about 1,6% of the total sales of medicines in pharmacies⁷.

In Poland, the prices of the medicines of the reimbursed medicines are set by the Ministry of Health at the national level according to the Act of the Reimbursed Drugs, i.e. they are the same in all the pharmacies in the country. The National Health Fund (NFZ) is the institution in charge of the reimbursement. This has a limit, and when the price of the medicine is over the threshold, the patient has to pay the difference. Parallel importers are free to set the price of pharmaceuticals, except for the reimbursed drugs, whose price is set by the Ministry as mentioned above.

There are no specific policies in place to incentivise the dispensing of parallel imports in pharmacies. The biggest advantage of PI medicines is their lower price compared with the reference medicine, making it more competitive and attractive for the patients. Pharmacists are obliged to inform the patients if a less costly substitute is available for the patients' treatment, but it is up to them to decide which product to buy.

For hospitals, medicines are purchased in public tenders that are regulated by the Act on Public Procurement. Unlike the price-setting mechanism concerning medicines for pharmacies, tenders are done at the hospital level. The main criteria for the selection are price, delivery time and payment terms.

The Polish Association of Importers of Parallel Medicinal Products (SIRPL) commissioned an analysis of the impact of parallel imports on the competition in the pharmaceuticals market. The objective of this study was to present the direct and indirect savings provided by parallel imported medicines in the Polish market during the period 2010-2018, as well as how they were distributed between pharmacies and hospitals.

⁷ Data from IQVIA and EFPIA.

The results were audited by the consulting company Deloitte.

The analyses of the savings take into consideration the savings of hospitals, patients and the National Health Fund. Sales information was obtained from IQVIA. Additionally, data published by the National Health Fund about the quantity and value of the reimbursed drugs in the period was retrieved from the website of the Polish Ministry of Health. The average price for each reference medicine was calculated on the basis of the reference amount and value of sales in each month from January 2010 to December 2018.

The **direct savings** were calculated using the standard methodology: the price difference between the price of the reference drug⁸ and its correspondent parallel import was multiplied by the amount of PI sold in the period. They amounted to **€42 million (zł 181.7 million) in 2018** and a combined **€189 million (zł 814.6 million) for the period 2010-2018**. Most of these savings came from the sales of parallel imports in pharmacies, and just a small proportion (about 1.5%) from sales to hospitals.

The methodology for the calculation of the indirect savings required the estimation of a counterfactual price, i.e. the price that the manufacturer would have set if it was not facing the competition from parallel imports. The approach chosen for this study was to use the price of the reference drug during the first month the PI corresponding product was present in the market. The difference between this price and the actual reference price of the originator's medicine throughout the period is the basis for the calculation of the indirect savings. These were only obtained when the PI product was being supplied in the market.

The **indirect savings** from the sales of parallel imports in Poland amounted to **€57 million (zł 244,3 million) in 2018** and **€467 million (zł 2 billion) in the period 2010-2018**. Around 2-3% came from the hospital sector, while the rest came from pharmacies. Although the savings in

⁸ A reference medicine is the originator's product available in the Polish market under which the parallel importers register the medicine.

Savings in EUR million	Direct savings	Indirect savings	Total savings
Pharmacies	41.6	55.2	96.8
Hospitals	0.6	1.6	2.2
Patients	15.4	-	15.4
National Health Fund	9.5	-	9.5
Total	67.1	56.8	123.9

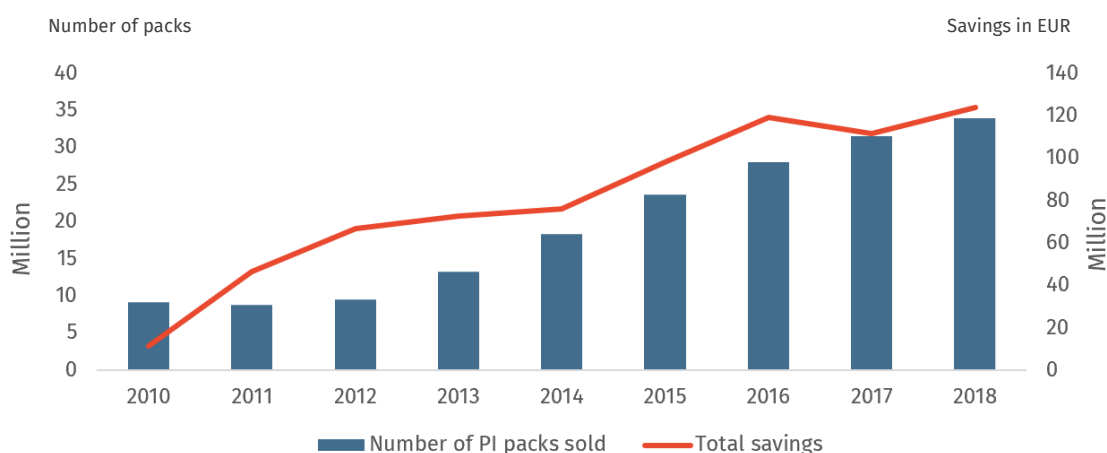
hospitals represent a small proportion of the total indirect savings, the competitive pressure is significant for a number of medicines. The study presents cases in which the entry of parallel imports has driven a reduction of the originator's price, both for the pharmacy and the hospital sector.

Another key feature of this analysis is that it presents the distribution of the savings between the National Health Fund (the public payer) and the contribution of the patients for reimbursed medicines. In 2018, more than **€15 million were saved by patients** due to the more affordable parallel import alternatives, and almost **€9 million were saved by the National Health Fund**.

In total, adding the direct, indirect and the ones coming from patients and the National Health Fund for reimbursed medicines, **savings in Poland amount to €124 million in 2018**, and €728 million for the period 2010-2018.

The savings generated by the distribution of parallel imports in the Polish market have steadily increased in the period analysed, as the number of packages sold in the market went from 9.2 million in 2010 to 33.7 million packs in 2018. The number of parallel imported medicines distributed in hospitals, while considerably smaller, has also experienced a significant increase: from 64 thousand packs in 2010 to 292 thousand in 2018.

There is scope for a greater growth of the savings from parallel imports in Poland. However, there are significant obstacles for their development. One of the most important is the 25% discount over the reference medicine price for the parallel import to enter the reimbursement scheme. Parallel imported medicines are effectively treated as if they were generics, when, in fact, they should be equivalent to the originators' products. This requirement hinders competition and increases the spending of the National Health Fund in medicines.



Evolution of the savings (in € million) and the number of PI packs sold (in million) in Poland in the period 2010-2018. Source: SIRPL (2019).



HOW FRAMEWORKS FOR PARALLEL IMPORTS COULD BE IMPROVED: THE CASE OF POLAND

The drug reimbursement system in Poland is regulated by the Reimbursement Act of 12 May 2011 which came into force on 1 January 2012. The Act provides for a parallel importer to act as an applicant, but does not provide for parallel imported products as a separate subject of the application.

In accordance with art. 2 section 27 of the Act, a parallel importer may apply for reimbursement and the public price of its product.

By art. 13 section 6 of the Act the price of any parallel imported product may not be higher than 75% of the price of the originator. In case that there are more products in the same basket of products (in case of generic medicines with the same active substance) the price of parallel imported product must be lower than the price of the product setting the reimbursement limit.

When there are different active substances in the same basket of products (the so called "Jumbo Groups" of products), the parallel imported product must be cheaper than the product which sets the reimbursement limit in that Jumbo Group.

For patented products, a parallel imported product must be at least 25% cheaper than the originator's equivalent, even though the originator had already been reimbursed with a public price set at a higher level. As a consequence, the same product has two public prices: one, higher, applied for the originator; and a second, 25% lower, applied for the parallel importer. In many cases, a 25% price difference is not economically sustainable for a parallel importer to get listed, while at the same time, the originator markets its product without any competition at a higher price.

After the patent expiry, even when the originator product is still on the market, the parallel imported product must be cheaper than one of the generics (the one setting the price limit).

Moreover, parallel imported products must comply with other conditions including the continuity of deliveries together with the annual volume of deliveries specified on a monthly basis, whereas parallel importers cannot control their supply sources.

The Reimbursement Act of 12 May 2011 clearly violates the EU principle of free movement of goods, and discriminates parallel imported products without objective justification. The current unequal conditions mean that a significant number of cheaper medicinal products cannot be reimbursed because they are unable to comply with the statutory requirements.





CONCLUSION

This new set of studies continues to bring sound evidence of the undeniably positive effects of parallel imports in Europe. The results corroborate the existence of sizable savings in the import markets and provide a solid framework for the quantification of the direct and indirect savings.

On the one hand, the direct savings figures obtained in the different studies are consistent with the results of the other countries and with previous studies on the same topic. After all, the methodology is straight forward, and relies on the vast price data owned by the Affordable Medicines Europe membership.

Indirect savings, on the other hand, are in most cases even larger than the direct savings, although seizing their magnitude requires a deeper understanding of the market and a more sophisticated methodology. The studies analysed in this report offer consistent and comprehensive approaches that reflect the competitive pressure exerted by parallel imports in the pharmaceutical markets.

Total savings in Denmark, Sweden, Poland, and Germany amount to more than 3.2 billion euro in one year. Savings translate into more affordable medicines for patients, better profitability for pharmacies or a substantial relieve in the health budget of the European governments.

However, despite the considerable amount of savings found in these four countries, there is still a lot of potential to be unlocked for parallel trade. In terms of incentives, it is necessary to promote the purchase of parallel imported medicines when they are the most affordable alternative.

More importantly, remaining barriers to the parallel import (and parallel export) of medicines across Europe must be removed. Not only does unjustified restrictions to parallel trade go against EU law and the foundations of the Internal Market; but also, they prevent some countries from benefiting from a more competitive pharmaceutical market.

National government and European institutions should realise the tangible benefits of parallel trade and create the appropriate framework for it to flourish in every country, not only those with higher income levels. There is scope for everyone to benefit from more competition and lower prices for pharmaceuticals.



AFFORDABLE MEDICINES EUROPE

WE REPRESENT

5.5Bn

Industry
turnover

125+

Individual
companies

23

EEA countries
cover

80%

Share of PI
market

**WORKING IN PARALLEL FOR A
BETTER DEAL**



BENEFITS OF PI: A BRIEF LITERATURE REVIEW

This section will provide a short overview of some of the most relevant publications on savings from parallel trade that have been published in the last two decades.

- Researchers from the University of York elaborated in 2003 a paper on the benefits of parallel trade for patients and taxpayers (West & Mahon, 2003). They estimated the direct savings for five countries (UK, Germany, Sweden, Netherlands and Denmark) in 2002 added up to €635 million. Evidence of competitive effects bringing prices of the medicines down in these countries was found, although indirect savings were not estimated in the paper.
- In 2004, the industry responded with a paper commissioned to the LSE (Kanavos, Costa-i-Font, Merkur, & Gemmill, 2004), in which the savings from six product categories accounting for 21% of the brand retail market were estimated. They concluded the savings were not significant enough to justify parallel trade. However, a later study by researchers from the University of Southern Denmark deemed this methodology inappropriate, as some of the products selected for the study were not subject to parallel import in all the countries considered or during the entire period (Enemark, Pedersen, & Sørensen, 2006).

In most cases, the products chosen for the study were not even in the top ten list of parallel drugs regarding sales in the period and countries analysed. Therefore, the LSE study largely underestimated the savings from parallel trade in their paper.

- With a more appropriate methodology, the study of Enemark, Pedersen and Sørensen calculated direct savings for Denmark, Sweden, Germany and UK that added up to €441.4 million in 2004. They also estimated the indirect savings for Denmark and Sweden for a combined €24.7 million. It is very likely that these indirect savings are underestimated due to methodology constraints.

The same group of researchers updated their analysis of the savings for the period

2004-2009 (Enemark & Pedersen, 2011). In this case they estimated the savings in Denmark, Germany and Sweden, that amounted to an average of €418 million annually. Germany had the largest share of the savings with 289€ million.

- Affordable Medicines Europe (formerly EAEPC) published in 2013 a report that built on the results of Enemark and Pedersen and used the same methodology to calculate the savings for a larger set of countries (EAEPC, 2013). Savings in emerging markets as France, Ireland Italy were smaller than in the main PI markets, but still not negligible. Savings amounted to €39 million in France in 2011 and €22 million in Poland in 2009. The savings for Denmark, Germany and Sweden were also updated for the period 2009-2012.
- Another study in 2016 took a different approach: it analysed the potential effects of removing parallel imports on prices and government and patients' health expenditure (Mendez, 2016). A researcher from the University of Melbourne developed a model based on the Danish Market for Statins and found out that a ban on parallel imports would increase the prices of patented medicines and also generics, although this increase would be even larger if the medicine is still under patent protection. The healthcare expenditure of the government would increase while the consumers' welfare would decrease.



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AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

Affordable Medicines Europe is the association of parallel importers and exporters of pharmaceuticals, and it represents more than 120 companies operating in 23 countries of the European Economic Area. The mission of its members is to offer a better deal for original European supply.

Parallel importers purchase medicines from pharmaceutical wholesalers in other EU/EEA member states, and sell them in the national market at a lower price in compliance with the regulation of the recipient country. Parallel imports of pharmaceuticals create competition in a business where patents provide the rights owners with a monopoly. This competition leads to reductions of the price and the creation of savings.