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WORKING IN PARALLEL FOR A BETTER DEAL



TRADE FLOWS OF PARALLEL IMPORTED MEDICINES

A closer look at the origin of PI medicines in Europe

June, 2020


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FOREWORD

The increasing prevalence of shortages around the EU is a key concern for Affordable Medicines Europe. Parallel trade is occasionally mentioned as one of the causes. However, evidence points towards other issues such as manufacturing disruptions, commercial withdrawals, supply quotas, etc.

The proportion of sales of parallel traded medicines with respect to the whole market of medicines has been continuously decreasing over the last decade and it currently represents below 2.9% of the total sales of medicines in Europe.

Affordable Medicines Europe and its members cooperate with authorities, other stakeholders and NGOs to alleviate shortages. Our members are firmly committed not to export medicines in shortage, and we accept restrictions on exports as long as these are proportionate and appropriate as prescribed by the EU Treaty. However, we will object if these restrictions are unproportionate and only take into consideration the interests of pharmaceutical manufacturers.

Affordable Medicines Europe's members help alleviate shortages every day by importing medicines that are lacking in a given Member States from Member States with excess supply. Especially those Member States with smaller populations can face commercial indifference from manufacturers, leaving parallel import as the only source of medicine supply.

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 nurture and maintain; a system which is currently under attack.



Kasper Ernest

Secretary General

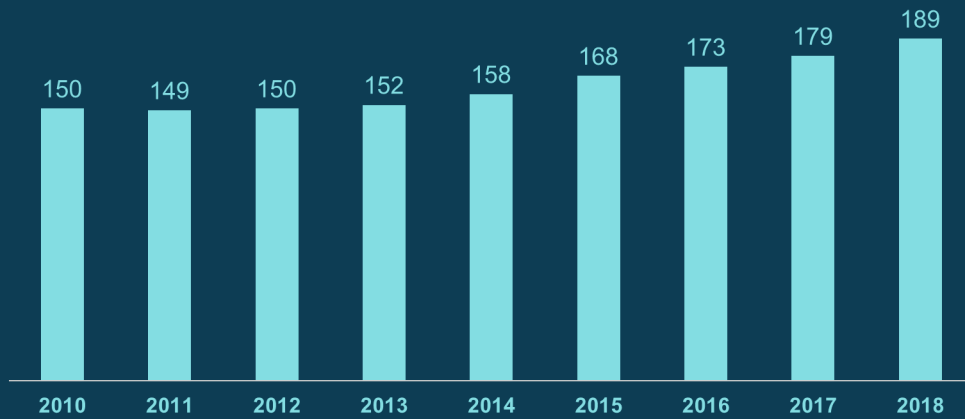
Affordable Medicines Europe

Such attacks are partially possible because of some of the myths surrounding parallel trade.

One such myth is the unidirectional travel of medicines from low-income to high-income countries. In this study we establish the facts around the parallel trade flows in Europe. We hope it will contribute to a sound discussion of shortages and how all stakeholders in the medicines supply chain can contribute in alleviating them.

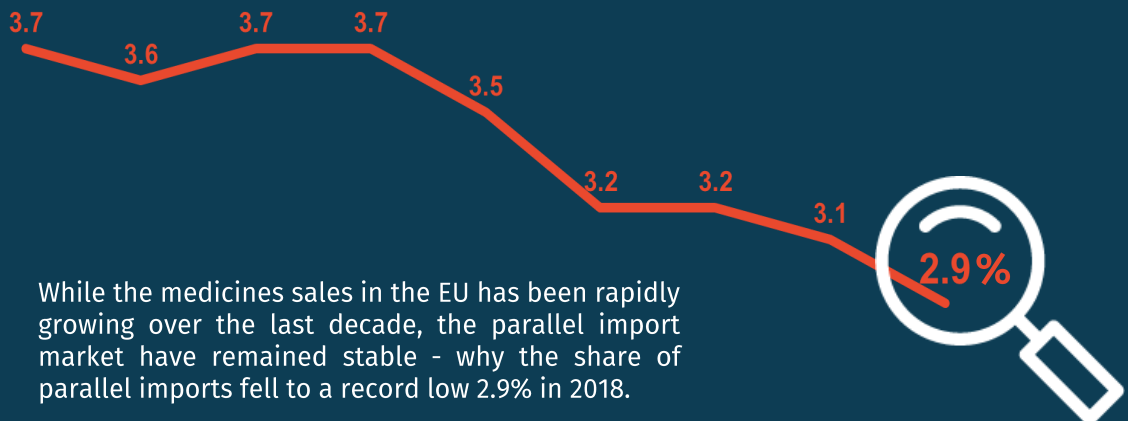
Kasper Ernest
Secretary General

Turnover EU medicines market in billion €



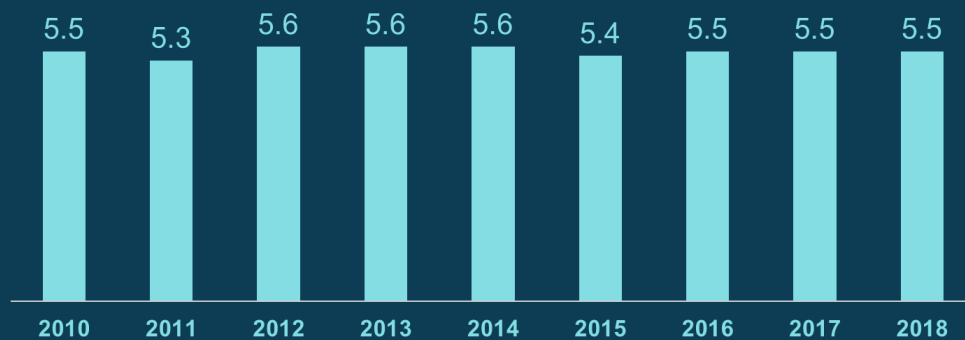
Source: EFPIA

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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WHAT IS PARALLEL TRADE?



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 import 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

As the prevalence of shortages is becoming a big challenge for healthcare systems all around the globe, a perception has arisen in Europe that parallel trade of pharmaceuticals is a one-way street, where the medicines go from lower income countries to higher income countries. Following this narrative, parallel imports would go from the south to the north and from eastern countries to western countries, provoking supply problems in the exporting countries as a consequence.

Although these ideas have spread across the continent and appear occasionally in the political debate, they are not based on strong foundations.

First, there is little evidence available that links the problems of supply of medicines in European countries with the parallel export of these medicines. There is already a number of export restrictions systems in place to prevent the departure of medicines at risk of shortage, with sanctions on those who do not respect them.

Second, until now, there is no or very limited knowledge about the direction of the parallel trade flows. Therefore, it cannot be assumed

that countries with a lower level of income are losing out from parallel trade.

The objective of this study is to analyse the origin of the parallel imports across Europe to understand better the trade flows of pharmaceuticals and assess the validity of this statement. This study is only possible thanks to the rich and vast parallel imports data provided by Affordable Medicines Europe's membership, that cover a big majority of the total PI sales in EEA countries.

Affordable Medicines Europe conducted a survey among its membership that resulted in 50 submissions from 14 countries: Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Poland, Spain and Sweden. These cover 85% of the total PI sales in Europe¹. Companies were asked about the original source country of the imports by country in % of value and their market share

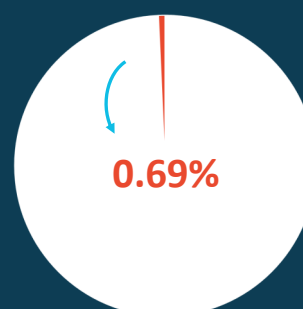
This report will first summarise the main trends found in the data, and then it will provide a country by country analysis of the results. ■

¹ Data from IQVIA

The majority of medicines in shortage today are generic medicines. According to Medicines for Europe, 29% of pharmaceutical expenditure in Europe is on generic medicines. This translates to € 48.1 billion in 2018 according to data provided by EFPIA.

At the same time, parallel import of generic medicines accounted for 6% of the total parallel import market of € 5.5 billion in 2018 according to IQVIA. This means that parallel imports of generic medicines is less than 0,7% of the total generics market.

Parallel trade in generics





About the data

Affordable Medicine Europe asked its members to provide the data necessary for the study of the trade flows of parallel imported medicines. The following information was gathered:

1. The original source country of the imports by country in % of value (in €) for the year 2018².
2. The market share of the company in the national PI industry in 2018.

The study is built on 50 submissions from the 14 countries that have been included in our study. The requisite for a country to be part of the analysis was that the companies that submitted the data covered more than 70% of the total national PI sales³. In most cases, there were data available to account for more than 90% of the total PI sales.

The countries included in the study are Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Poland, Spain and Sweden. These cover 85% of the total PI sales in Europe⁴.



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
- UK

Aggregation and analysis

The data was anonymised and aggregated at the national level, both for analytical and business purposes. The aggregation was made according to the market share of every company and their reported origin countries. The results were extrapolated for the whole national market where they did not cover it completely⁵.

European weighted average

$$= W_1C_1 + W_2C_2 + W_3C_3 + \dots$$

w_i = pct. of the total sales of PI in Europe of country i

c_j = vector with the aggregated pct. of sales by country for the country j

Then, results were aggregated at the European level. In order to do this, the results of each country were weighted by the percentage of the total European PI sales that they represented. Therefore, countries with a higher volume of PI sales have a larger weight in the calculation of the average. Results were extrapolated to account for the remaining sales in Europe not covered by the data.

national weighted average

$$= W_1C_1 + W_2C_2 + W_3C_3 + \dots$$

w_i = market share of company i

c_j = vector with the pct. of sales by country for the company j

Additionally, gross domestic product and population information was retrieved from Eurostat to calculate some of the variables. ■

² It is a legal obligation for all parallel importers to know the exact origin country of all the products they import. Most data collection services can only gather trade data, which indicate where a product was bought – not its origin.

³ Poland is the exception, where the data covered 44% of the market.

⁴ Data from IQVIA.

⁵ Data from IQVIA.



RESULTS: THE ORIGIN OF PARALLEL IMPORTS

More than half of the parallel imports in Europe are sourced in high-income countries. The evidence proves that there are no foundations to south to north/east to west trends of parallel imports' flows. The distribution among northern, southern and eastern countries is considerably homogeneous in the top 10 origin countries from which parallel imports come.

The key component missing so far in the debate around parallel trade in the EU/EEA has been an understanding of where products actually originate – that means where they were originally marketed by the pharmaceutical manufacturer to then be transferred to another EU country by parallel trade. Capturing this trade flow is possible as parallel importers are legally obliged to keep on record the origin country of the products they import.

The study is based on data received from Austria, Belgium, Bulgaria, Denmark, Finland, France,

Germany, Ireland, Italy, Netherlands, Norway, Poland, Spain, Sweden.

Results for total trade in value

The analysis revealed that 51.3% of the parallel imports in Europe in terms of euro value originate from high-income countries (please see methodology for the 12 countries considered high-income in this analysis). That may be medicines going from e.g. UK to Denmark or from Germany to Poland.

The same trend can be observed at the national



51%

of parallel imports come from high-income countries



Top source/export countries in 2018:

- 1. France**
- 2. United Kingdom**

level in nine out of the fourteen countries, where more than 50% of the PI come from high-income Member States (Austria, Belgium, Denmark, Finland, Germany, Netherlands, Norway, Spain, and Sweden). In the next chapter a separate overview of all 14 countries will be provided.

Spain is country with the highest proportion of its parallel imports originating from high-income countries: 67.1 percent of parallel imports into Spain comes from high-income countries.

The results also show that France and UK are the two main sources of medicines in the EU/EEA. In the context of Brexit, it is noteworthy that al-

the size of their markets, an analysis was furthermore conducted to consider parallel exports per capita.

The results showed that the country exporting most medicines per capita is Norway. The average European export per capita was 16.4 euro. **Both France and the UK exported less than average per capita despite being the largest exporters in terms of total volumes.**

A number of countries often considered to be lower-priced exporting countries such as **Hungary, Italy, Poland, Spain, Estonia, Croatia, and**

Norway exports more per capita than any other EU/EEA country

most 10.8% of all imports to the EU27/EEA originates from the UK. **Neither France nor the UK are amongst those countries exporting most per capita** (France and the UK is the 13th and 17th largest exporters per capita respectively).

Concerning the direction of the flows of parallel trade from a European perspective, the distribution is rather balanced. **A similar proportion of sales of parallel imported products is sourced in northern, southern and eastern countries.**

Results per capita

While the results in total volumes puts France and the UK in front, unsurprisingly considering

Portugal, export below or far below the European average. In contrast, countries often perceived as high-priced countries such as Norway (number one), Austria, the Netherlands and Belgium were above this average.

Like the UK, The Netherlands is a good example of a country where the imports and exports are in a good balance. The Dutch market sees almost the same amount of exports as imports. This means that Dutch excess medicines can help bring down prices in e.g. Poland or Bulgaria, while excess medicines from e.g. Germany or Austria can help lower prices in the Netherlands.

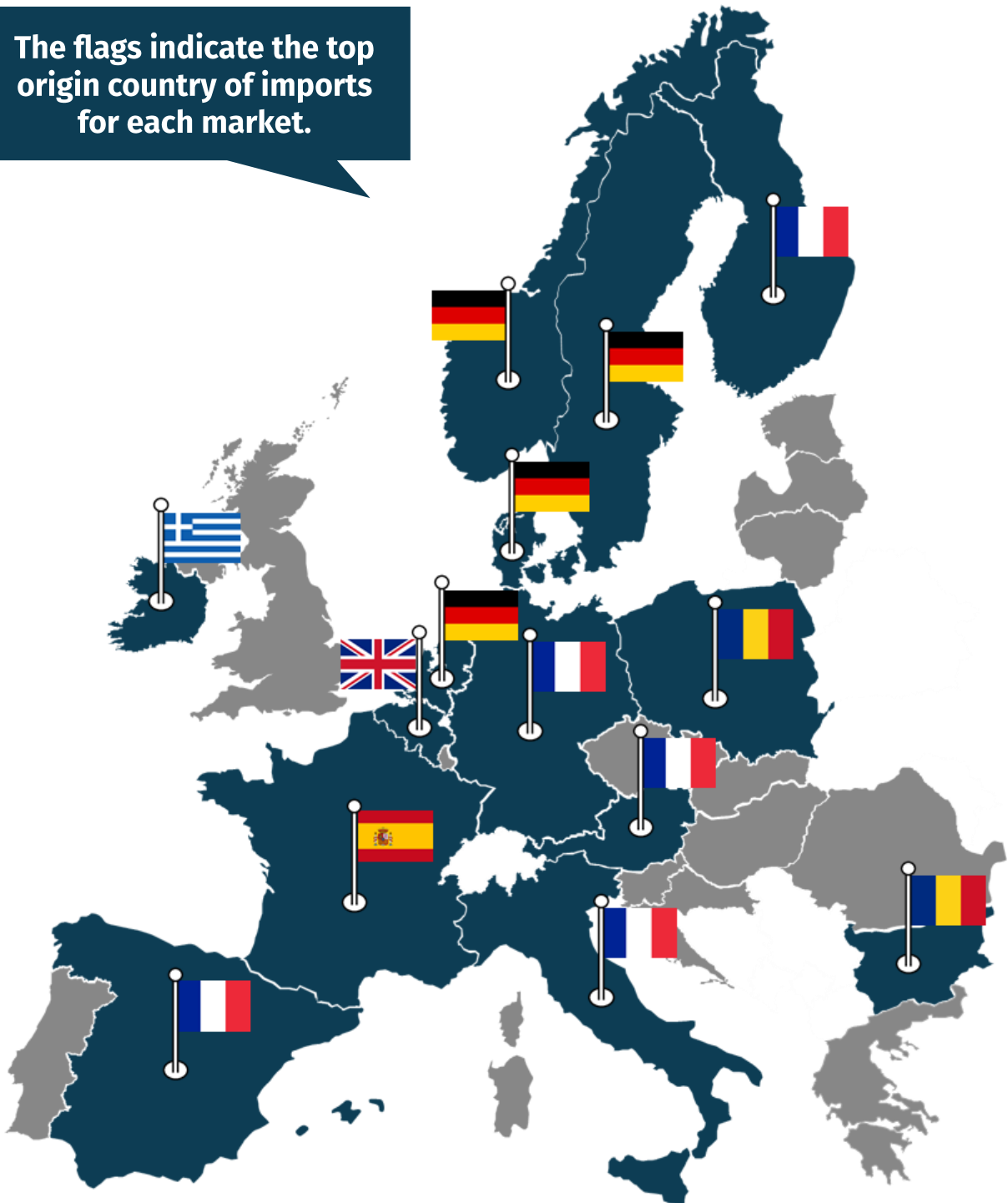


Country overview: More than half of parallel imports originate from high-income countries (%)

• Austria	52.9%	• Netherlands	53.9%
• Belgium	59.1%	• Norway	50.2%
• Denmark	52.6%	• Spain	67.1%
• Finland	55.0%	• Sweden	51.3%
• Germany	52.3%		

Main origin of parallel imports by country in € volumes

The flags indicate the top origin country of imports for each market.



The countries that participated in the study are coloured in blue. Countries that have no or very negligible parallel imports are not included in the study; Slovenia, Croatia, Romania, Hungary, Slovakia, Czechia, Estonia, Greece and Portugal. For some parallel importing countries sufficient data could not be obtained to include them in the study; UK, Lithuania, and Latvia.



OPPORTUNITIES FOR EVERY COUNTRY TO BENEFIT FROM PARALLEL IMPORTS

Parallel exports are sometimes uncritically connected with low-income Member States or the average prices of medicines across Member States. This assumption is not supported by the findings of the study. In fact, almost all Member States export medicines.

The prices of the medicines in Europe are set at the national level, and they are the result of multiple factors; strategies of the pharmaceutical companies, willingness to pay, delayed entry etc. Therefore, prices are not homogeneous across EU/EEA, which creates opportunities for arbitrage, i.e., importing medicines from another country at a lower price.

This is why parallel import is also an opportunity for those countries with a lower general price level for medicines, as prices for a range of medicines in that country may indeed be higher than elsewhere irrespective of the average of its prices. This is true in practice even where External Reference Pricing would in theory dictate otherwise.

As prices must be lower in the origin country than in the importing country for parallel trade to be viable, this cements the obvious logic that parallel trade is neither concerned with average prices nor income level in a given Member State; but purely with the price of the individual medicine in question. This is supported by the findings.

Also, there is a substantial difference in the variation of the prices across EU/EEA for medicines not exposed to competition (on patent) and exposed to competition (with generic alternatives in the market). While the price level of medicines without competition from generics are relatively higher in high-income countries, price spreads are not so big. However, differences are larger for medicines facing competition from generics, and Denmark, Sweden and Netherlands are the countries with the lowest price level. This means that there are opportunities for low-income countries to import these pharmaceuticals from high-income countries.

Analysis: The origins of imports not destined for Germany

Germany is the country with the biggest parallel imports industry in the EU/EEA. About half of the sales of parallel imported medicines in Europe take place in Germany. For this reason, the overall results for the origin of the parallel imports in the EU/EEA are significantly influenced by the trends in Germany.

An additional analysis was performed excluding the German imports from the calculations of the origin of the trade flows. These results are obtained from the aggregation of the origin of the imports data of all the countries included in the analysis except Germany.

The analysis reveals that Germany is the main source of parallel imported products for the rest of the EU/EEA (minus Germany), followed by France and the UK⁶. In other words, **Germany is not only the destination of a big portion of the parallel imports, but it is also the main exporter for the rest of the EU/EEA.**

In fact, Germany is the top source of parallel imports in Denmark, Sweden, Netherlands (respectively the 5th, 4th, and 3rd biggest import markets in the EU/EEA) and Norway, and it is in the top 3 origin countries in 9 of the 13 countries in the study (excluding Germany).

Discussion

While most academic literature, media reports, and political statements reiterate that parallel trade is concept whereby products flow from low-income to high-income countries in the EU based purely on theoretical assumptions, this study clearly dismantles this as a myth.

Due to the unique representativeness of Affordable Medicines Europe (80-85% market coverage of its membership) and the legal obligation of its members to collect this specific information, the data collected for this study is uniquely reliable and the only of its sort. Therefore this study is the first to give a clear picture of the true nature of the trade flows in the parallel distribution market in the EU/EEA.

Not enough data was available to include the UK PI market. However, the data received indicated the same trend as for all other main import markets; more the 50% of imports originate from high-income countries. ■

⁶ These results are obtained from the aggregation of the origin of the imports data of all the countries included in the analysis except Germany.



Germany is the main source of parallel imports in four of the largest import markets in the EU. The share of imports from Germany is:

- Sweden 13.8%
- Denmark 11.6%
- Netherlands 20.0%
- Norway 15.7%



Actually, Germany is one of the top 3 origin countries in 9 of the 13 import markets. Besides the four countries above where it is number 1;

- it is **2nd** in and **3rd** in
- Austria
 - Belgium
 - Poland
 - Finland
 - Spain



In total, Germany is the main exporter for the remaining EU/EEA market, while France and the UK follow in 2nd and 3rd place:

1. Germany 13.0%
2. France 12.5%
3. UK 10.6%



COUNTRY OVERVIEW



GERMANY

Germany accounts for more than half of the total parallel imports in the EU/EEA with a market of 2.9 billion euro/year, and it is very indicative that the main sources of Germany's imports are countries with a high GDP per capita.

Parallel imports are primarily sold in pharmacies in Germany with a market share of pharmacy sales of around 8%⁷.

In 2018, the total savings (direct and indirect) were above €2.8bn which goes directly to the German health insurers (Krankenkassen)⁸. Since July 2019, a new savings target of 2% has been put in place between the pharmacies and health insurers.

In total, 52.3% of the parallel imports into Germany are sourced in high-income countries. France, the UK, and Austria are the three main sources of German imports.

While Germany is the main EU/EEA market for imports, it is also the main exporter for the rest of the EU/EEA markets. The Netherlands, Denmark, Norway, and Sweden has Germany as the top source of their respective parallel import markets. Germany is also the second largest parallel exporter to Austria, Belgium and Poland, and the third largest parallel exporter to Finland and Spain.

Per capita Germany is the second largest importer, while for exports it is still below the European average despite it being the largest exporter to the remaining EU/EEA import market. This can be explained by the large total value of the German parallel import market.

The German market for as well parallel imports and parallel exports is expected to grow in the coming years. ■

⁷ Data from IQVIA and EFPIA.

⁸ Savings report 2020: <https://bit.ly/3cF9Ocf>.



Size of the import market:

€2.9bn

Share of the total EU market:

53.0%

Share of parallel imports from high-income countries:

52.3%

TOP SOURCES:

1. France

2. UK

3. Austria





NETHERLANDS

Sales of parallel imports in the Netherlands accounted for €450 million in 2018, which is around 8% of the total European parallel import market. This makes the Netherlands the 3rd largest parallel import market in Europe. As with Germany, it is very indicative that most imports to the Netherlands come from other high income Member States.

Parallel imports are an integrated part of the Dutch medicines supply chain. Most parallel imports to the Netherlands are sold in pharmacies. In fact, around 13% of all medicines dispensed in Dutch pharmacies are parallel imports⁹. It is the shared-second highest share (along with Sweden) in Europe after Denmark.

As in comparable markets such as Sweden, Denmark, and Germany, savings in the Netherlands are considered to be significant. These include also savings in the hospital sector where parallel imports also are a part of the supply chain.

Parallel imports to the Netherlands are also primarily sourced in the 11 other Member States with the highest GDP per capita. In total, almost 54% of imports come from the other highest income countries.

The main sources of these products are France, Germany and Italy (whereas Italy is not included in the 54% of highest income source countries). The Netherlands are above average both in parallel imports and parallel exports per capita.

In fact, the Netherlands, while being the 3rd largest parallel importer, are also among the top 10 most exporting countries in the EU/EEA. In other words, the value of parallel imports and parallel exports are almost the same. Hence, the Netherlands is close to having a neutral parallel trade balance. ■

⁹ Data from IQVIA.

TOP SOURCES:

1. **Germany**

2. **France**

3. **Italy**



Size of the import market:

€450m

Share of the total EU market:

7.9%

Share of parallel imports from high-income countries:

53.9%



DENMARK

Denmark is the 5th largest parallel import market in Europe. However, per capita, Denmark is by far the largest parallel importer.

The Danish pharmacy tender system is the primary cause of the success of parallel imports in Denmark. With transparent national 14-day tenders for all pharmacy supply, parallel importers can take full advantage of the competitive pressure from parallel trade. As a result, around 26% of all medicines dispensed in Danish pharmacies are parallel imports¹².

Parallel imports also have a noticeable share of the hospital market at around 7.5%. This is partially explained by the high prices of specialty medicines in Denmark.

Savings from parallel imports in Denmark goes to the State at the regional level, since the Re-

gions are responsible for the provision of healthcare in Denmark, including medicines.

Recently, Copenhagen Economics estimated that savings from parallel imports in 2018 amounted to €82 million. This corresponds to almost 3% of the total medicines expenditure in Denmark that year¹³.

In total, almost 53% of parallel imports to Denmark are sourced in the 11 other Member States with the highest GDP per capita. As with the other big parallel import markets, Germany, France, and the UK are the three main sources for Danish parallel imports.

Denmark has almost no exports. This is primarily due to the high prices of specialty medicines, as well as the specific structure of the market for most generics. ■

¹² Data from IQVIA and EFPIA.

¹³ Savings report 2020: <https://bit.ly/3cF9Ocf>.



Size of the import market:

€360m

Share of the total EU market:

6.5%

Share of parallel imports from high-income countries:

52.6%

TOP SOURCES:

1. Germany

2. France

3. UK





SWEDEN

Sweden was the 4th largest parallel imports market in 2018. Sales of parallel imports amounted to roughly 400 million euro that year, only surpassed by Germany, the UK, and the Netherlands (€2.8 billion, €850 million, and €450 million respectively).

Parallel imports are an integrated part of the Swedish medicines supply chain. While Sweden in total terms is a smaller market than Germany and the UK, the share of parallel imports in the pharmacy sales market is higher at 13%¹⁰. This is the second highest share (with the Netherlands) in Europe after Denmark.

Parallel imports also play a role in the hospital sector, albeit a smaller one than for pharmacy dispensed medicines.

Savings from parallel import to Sweden goes to the pharmacies and hospital counties. In 2018, savings from parallel import amounted to €235 million in the pharmacies alone¹¹. In fact, when

competition from parallel imports are introduced for a given product, it leads to a drop of the originators revenue with 17% on average.

Parallel imports to Sweden are also primarily sourced in the 11 other Member States with the highest GDP per capita. In total 51.3% of imports come from the other highest income countries. The main sources for Sweden are Germany, France, and the UK.

Sweden is not a large export market, primarily due to the structure of Swedish supply chain and regulatory hindrances for exporters. Hence, there is potential for further exports. Also, as the Swedish krona is not pegged to the euro, exchange rate fluctuations play an important role if other barriers were removed. ■

¹⁰ Data from IQVIA and EFPIA.

¹¹ Savings report 2020: <https://bit.ly/3cF9Ocf>.

TOP SOURCES:

1. **Germany**

2. **France**

3. **UK**



Size of the import market:

€400m

Share of the total EU market:

7.3%

Share of parallel imports from high-income countries:

51.3%



IRELAND

Ireland was first among the second tier parallel import markets in 2018 (markets with under €300 million turnover). In 2018 the turnover of parallel imports was approximately €130 million. It is a market in rapid growth, and numbers for 2019 indicate a growth of around 14% (same level as 2018 growth).

Parallel imports are an integrated part of the Irish medicines supply chain. While Ireland in total terms is a far smaller market than Germany and the UK, the share of parallel imports in the pharmacy sales market is higher at 8.5%¹⁴. In Also, per capita, Ireland is in fact the 3rd largest parallel import market in Europe.

Savings in Ireland are considered to be significant, as in comparable markets like Sweden, Denmark, and Germany.

The main sources of parallel imported medicines in Ireland are Greece, the UK, and France. Having a lower-income country as its main source in 2018 makes Ireland a bit of an outlier amongst the high income countries.

This outlier status is also confirmed by the fact that 'only' 33% of the parallel imports in Ireland are sourced in the other 11 highest income countries in the EU/EEA.

As individual parallel imported products (blockbusters) may play a larger role in smaller markets, this outlier status may be a consequence of this. However, the data available does not allow for that level of analysis.

Ireland has a relatively low level of exports per capita placing it 22nd in the EU/EEA. Ireland will be among the most affected by Brexit in its parallel trade market. ■

¹⁴ Data from IQVIA.



Size of the import market:

€130m

Share of the total EU market:

2.4%

Share of parallel imports from high-income countries:

33.0%

TOP SOURCES:

1. Greece

2. UK

3. France





ITALY

Italy had a parallel import market of approximately €120 million in 2018. This puts Italy among the large second tier parallel import markets in Europe (€50-300 million). Nevertheless Italy is one of the smaller parallel import markets in Europe per capita—behind Poland, for example.

In recent years, Italian parallel imports had been growing rapidly. However, since 2019 the market has stagnated. This is primarily due to issues with lack of reimbursement for parallel imports. The Italian parallel import sector estimate that the market could triple in a few years, if the Italian authorities were to provide a level playing field between them and pharmaceutical manufacturers.

Savings for the Italian market have not been quantified in later years, but are estimated to be comparable to savings obtained from parallel imports in Poland (In 2018 Poland saved €124 million due to parallel import competition)¹⁵.

The main sources for Italian parallel imported medicines are France, Poland, and Spain. Despite having Spain and Poland among the top three sources, Italy still source more than 47% of their parallel imports from the 12 highest income countries in the EU/EEA. The UK and Germany are the 4th and 5th largest source countries for Italy.

While Italy is considered a traditional parallel export market with the 5th largest total parallel export value, it is actually among the smaller export markets per capita. In fact, per capita Italy is only the 19th largest parallel export market in Europe. Italy nonetheless has export restriction legislation in place, and export bans for some products have been imposed since ■

¹⁵ Savings report 2020: <https://bit.ly/3cF90cf>.

2019.



Size of the import market:

€120m

Share of the total EU market:

2.2%

Share of parallel imports from high-income countries:

47.2%



POLAND

Poland had a parallel import market of approximately €100 million in 2018. This puts Poland among the large second tier parallel import markets in Europe (€50-300 million). Considering that the Polish parallel import market is among the younger in the EU (parallel trade has only been possible since Poland joined the EU), it has developed quickly, and is today an important contributor to the Polish medicines market.

Savings in Poland have been substantial over the past decade. In 2018 alone, parallel imports to Poland resulted in savings of €124 million for the Polish healthcare system and patients (patient co-payment falls as prices are pushed down)¹⁶.

Romania, Germany and UK are the three main sources of parallel imports in Poland. In total,

approximately 35% of the imports to Poland are sourced in the 12 highest income countries in the EU/EEA.

The Polish import market could be significantly larger, but the framework for parallel imports in Poland is overly restrictive in terms of obtaining reimbursement.

While Poland is a net-parallel exporting country, it is in fact not among the top 10 exporting countries in terms of total value. Furthermore, exports per capita is among the lowest in Europe (18th largest exporter per capita). Nonetheless Poland has introduced unproportionate parallel export restrictions. This makes Poland one of the few countries that openly acknowledge the benefits from parallel imports while infringing EU law in relation to parallel exports. ■

¹⁶ Savings report 2020: <https://bit.ly/3cF9Ocf>.



Size of the import market:

€100m

Share of the total EU market:

2.0%

Share of parallel imports from high-income countries:

35.0%

TOP SOURCES:

- 1. Romania**
- 2. Germany**
- 3. UK**



FINLAND

Finland had a parallel import market of approximately €80 million in 2018. This puts Finland among the smaller second tier parallel import markets in Europe (€50-300 million). Nevertheless Finland was the 6th largest importer per capita in 2018.

In recent years, Finish parallel imports have been growing rapidly, and recent data from 2019 suggest the market is nearing €100 million turnover. Sensible incentives for parallel imports are among the reasons for this growth.

Savings from parallel imports in Finland have not been quantified in recent years, but are considered to be comparable to the savings accrued by parallel imports in Denmark and Sweden (adjusted for size of the market)¹⁷.

Finland has one of the highest shares of parallel imports sourced in the 11 other highest income

countries at 55%. The three main sources of parallel imports are France, the UK, and Germany. Norway, the Netherlands, and Austria are among other large sources for the Finish parallel import market (the 4th, 7th, and 10th largest sources respectively).

The Finish market for parallel imports of medicines is expected to grow further in the coming years, as the market is still trailing somewhat behind some of the other large import markets.

Finland has almost no parallel exports. This is primarily due to the high prices of specialty medicines and the structure of the Finish medicines supply chain. ■

¹⁶ Savings report 2020: <https://bit.ly/3cF9Ocf>.



TOP SOURCES:

1. **France**

2. **UK**

3. **Germany**



Size of the import market:

€80m

Share of the total EU market:

1.5%

Share of parallel imports from high-income countries:

55.0%



AUSTRIA

In 2018 parallel imports to Austria amounted to €60 million in total value. However, Austria is the fastest growing parallel import market in Europe, and with explosive growth rates of +50% estimates for 2020 puts the market above €120 million.

The explosive growth in parallel imports in Austria is primarily found in the hospital sector. Hospital tenders are often smaller and for shorter than usual periods. These are beneficial conditions for parallel imports, whereby competition is significantly spurred.

Savings in Austria have not been quantified, however, as the individual hospitals/buying alliance of hospitals directly get the savings via their tenders. These savings are considered to be significant.

The growth in the Austrian market is expected to continue in the coming years, albeit whether the recent growth rates can be maintained remains to be seen.

As with most other parallel import markets, more than half of the medicines come from the 11 other highest income countries. In total almost 53%. France, Germany, and Romania (not counted among the highest income countries) were the three main sources of parallel imports in Austria in 2018. Norway and the UK follow closely after at 4th and 5th place respectively.

Austria is one of the larger parallel export markets in Europe. Both in terms of total value and per capita Austria is in top 10. In fact, per capita Austria is the 3rd largest parallel exporter, while in total value Austria is the 8th largest. Austria has legislation in place to restrict parallel exports of medicines in shortage. ■



Size of the import market:

€60m

Share of the total EU market:

1.0%

Share of parallel imports from high-income countries:

52.9%

TOP SOURCES:

1. France

2. Germany

3. Romania





BELGIUM

Parallel imports sales in Belgium amount to approximately €60 million in 2018. However, Belgium is the second fastest growing parallel import market in Europe, and with growth rates of around 30% the market had already reached the size of €80 million euro in 2019.

The growth in Belgium takes place despite extraordinarily problematic procedures for obtaining parallel import licenses. Hence, if the authorities were to improve their processes, imports could grow further. Also, in Belgium many medicine shortages could be solved through parallel imports.

With almost 60% of parallel imports sourced in the 11 other highest-income countries, Belgium has the second highest share of imports from the highest-income countries. The UK, Romania (not counted among the high income source countries), and Germany were the main sources of parallel imports in 2018.

Belgium is extraordinarily dependent on parallel imports from the UK— at almost 30% of total parallel imports sourced there. Hence, the Belgian parallel import market may experience some changes, if a hard Brexit became a reality in 2021.

Belgium is not among the larger parallel export markets in Europe in total value. In 2018 Belgium was 13th. Per capita Belgium scores slightly higher as the 11th largest parallel export market. Still, parallel exports are not significant.

Considering the current growth of Belgian parallel imports, Belgium is expected to approach neutrality in trade balance between parallel imports and exports in the coming years. Belgium has legislation in place to restrict parallel exports of medicines in shortage. ■



TOP SOURCES:

1. **UK**

2. **Romania**

3. **Germany**



Size of the import market:

€60m

Share of the total EU market:

1.0%

Share of parallel imports from high-income countries:

59.1%



NORWAY

Despite not being in the EU, Norway can participate in the parallel distribution of medicines as a member of the European Economic Area (EEA).

Parallel imports in Norway have been falling in recent years. Among the Nordic countries it is the smallest parallel import market at €50 million in 2018. Per capita, however, Norway is relatively close to e.g. the UK, and still in top 10.

The Norwegian parallel import is not very well incentivised, which leads to sub-optimal conditions and less savings from parallel imports than in the other Nordic countries. Also, prices of specialty medicines in Norway are among the lowest in Europe. This has also made Norway the largest parallel exporter per capita in all of the EU/EEA.

Norway also source half of their parallel imports from the 11 other highest income countries. Norway's top three sources of parallel import includes three high income countries: Germany, France, and the UK.

As mentioned Norway has the largest parallel export per capita. In total value, Norway is the 9th largest parallel exporter in Europe. While acknowledging that parallel exports is not a contributor to shortages in Norway, the Norwegian government has introduced legislation to restrict exports of medicines in shortage.

The future developments in the Norwegian market are difficult to predict. Despite the recent decline in the parallel import market, parallel importers are still investing in new licenses. Nonetheless, Norway have become a net-exporting country in recent years. ■



Size of the import market:

€50m

Share of the total EU market:

1.0%

Share of parallel imports from high-income countries:

50.2%

TOP SOURCES:

1. Germany

2. France

3. UK





FRANCE

France is still a very small market for parallel imports. With only €15 million in imports, it is one of the smallest per capita in Europe. However, the market has potential for growth in imports.

For the French parallel import market Spain, the UK, and Czechia are the three main source countries in 2018. In fact, almost half the imports come from Spain. This is primarily linked to one parallel imported product, which makes up a significant share of the parallel import market in France. At the same time, France is the top source for Spain.

France is the main source of parallel imported medicines in Europe. However, whilst being the largest parallel exporter in total value, France is only the 13th largest parallel exporter per capita. In fact France is under the European average in terms of exports per capita.

According to the French national medicines agency, the ANSM, parallel exports are not among the main causes of medicines shortages in the country. Rather, problems related to the pharmaceutical production (incidents of production or lack of quality, lack of raw material supply, insufficient production capacity in relation to sales volumes, etc.) have been identified¹⁷.

France has legal provisions to ban parallel exports for individual medicines in shortage. However, they have not been used (except for during the COVID-19 crisis). ■

¹⁷Cours de Comptes (2017). *La Sécurité Sociale. Rapport sur l'application des lois de financement*. Paris: Cours de Comptes. Retrieved from https://www.ccomptes.fr/sites/default/files/2017-09/20170920-rapport-securite-sociale-2017_1.pdf.



Size of the import market:

€15m

Share of the total EU market:

0.3%

Share of parallel imports from high-income countries:

17.0%



SPAIN

The size of the parallel import market in Spain is still small, as sales added up to approximately €12 million in 2018. Spain has been developing rapidly in recent years, and numbers for 2019 indicate an almost doubling of parallel imports to €20 million.

The main sources of parallel imported medicines in Spain are France, Poland and Germany. Spain has the highest share of parallel imports coming from the 12 highest income countries in the EU/EEA. In fact, 67.1% of the parallel imports to France comes from the 12 highest-income countries.

Just as French parallel imports primarily come from Spain, Spanish parallel imports primarily come from France—at well above 50%. Consider-

ing the small size of the Spanish parallel import market, individual medicinal products play a significant role in the trade flow pattern for the market. Hence, fluctuations in the Spanish market are dependent on the development of prices for just a few products.

Contrary to common belief, Spain's level of parallel exports per capita is relatively low and below the European average. In total value Spain is the 12th largest parallel exporter. However, in fact it is only the 21st largest exporter per capita. As a consequence, Spain is fairly close to having a neutral parallel trade flow balance.

Spain has export restriction legislation in place to ensure that medicines in shortage are not parallelly exported. This system is generally well managed, and exports are not considered among the main causes of shortages in Spain. ■



Size of the import market:

€12m

Share of the total EU market:

0.2%

Share of parallel imports from high-income countries:

67.1%

TOP SOURCES:

- 1. France**
- 2. Poland**
- 3. Germany**





BULGARIA

The Bulgarian market for parallel imports is relatively recent and its size is still small. Sales of parallel imports amounted to approximately €4 million in 2018. Parallel imports nonetheless have been developing quickly in Bulgaria in recent years. Also, they have been an important driver in alleviating shortages in Bulgaria.

In spite of being one of the lowest priced medicines markets in Europe, parallel imports also have a great potential in this market. Especially trade between Eastern European countries could be spurred further as companies enter the market and increase competition.

In 2018, Romania, Poland, and Hungary were the three main source countries for the Bulgarian parallel import market.

Despite being amongst the countries with the on average lowest medicines prices, more than 20% of parallel imports to Bulgaria still came from the 12 highest income countries.

According to the Bulgarian Association for Medicines Parallel Trade Development (BAMPTD), there is also a big potential for parallel imports to alleviate the problems of supply in the country¹⁸.

Bulgaria is the 13th largest parallel exporter in total value in Europe. Below countries like Norway, Austria, the Netherlands, and Germany. In terms of per capita, parallel exports are above average (7th largest), but still well below countries like Norway and Austria.

Bulgaria has legislation in place to restrict parallel exports for medicines in shortage. ■

¹⁸Voinova, L. (2019). *560 Missing Drugs Alerts*. Bulgaria: BAMPTD. Retrieved from <https://parallel-trade-development.org/en/news/BAMPTD-news/560-Missing-Drugs-Alerts>.

TOP SOURCES:

1. **Romania**

2. **Poland**

3. **Hungary**



Size of the import market:

€4m

Share of the total EU market:

0.1%

Share of parallel imports from high-income countries:

23.9%

CONCLUSION

The evidence collected by Affordable Medicines Europe proves that more than half of the parallel imports of pharmaceuticals originate in high-income countries. The flows of PI are similarly distributed across the continent, as the proportion of medicines sourced in northern, southern and eastern countries is comparable.

Medicines do not go from the south to the north or from east to west; trade flows occur in many directions, and many traditionally considered importing countries are at the same time big exporters. A higher percentage of the parallel imported medicines come from countries like the Netherlands or Austria than from Poland, Spain or Bulgaria.

France and UK are the main source countries at the European level, and Germany is the main source for the rest of Europe if German imports are excluded from the calculations. Germany is also in the top 3 of nine out of the fourteen countries in the study.

Price levels are not homogenous among and within markets. Although the general price level of medicines in one country might be higher than in another, there are very often particular cases in which a particular medicine is still relatively less expensive.

Every country can potentially benefit from parallel trade. The objective of parallel importers is not taking medicines from “poor” countries to sell them in “rich” countries to the benefit of the latter and detriment of the former; but identifying opportunities and promoting competition. It is key to remember that parallel imports are the only competition to the pharmaceutical manufacturers for medicines under patent protection.

Parallel imports produce savings direct and indirectly. In other words, they bring original medicines into the market at lower prices and they push the national prices down via competition. Not only that, but parallel imports also help to alleviate shortages by providing pharmaceuticals that are suffering from supply problems to the market.

In order to unlock the full potential of parallel trade, national governments should remove the remaining barriers to both import and export of pharmaceuticals. The European Commission should be a key player in this process, enforcing the free movement of goods across Europe and promoting competition at the EU level.





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**



NOTES



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.