AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

TRADE FLOWS OF PARALLEL IMPORTED MEDICINES 2020

- A closer look at the origin of PI medicines in Europe

September, 2021

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Editor: Esco Aguiar
Publisher: Affordable Medicines Europe

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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, quality problems, 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 2.8% 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 State 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.

The COVID-19 crisis has shown the perverse negative effect of export restrictions. Restricting free movement of goods will decrease access to medicines. On the contrary, keeping parallel imports available to all countries, while assuring exports are never causing shortages, leads to the healthy parallel trade eco-system we advocate to nurture and maintain; a system which is currently under attack.

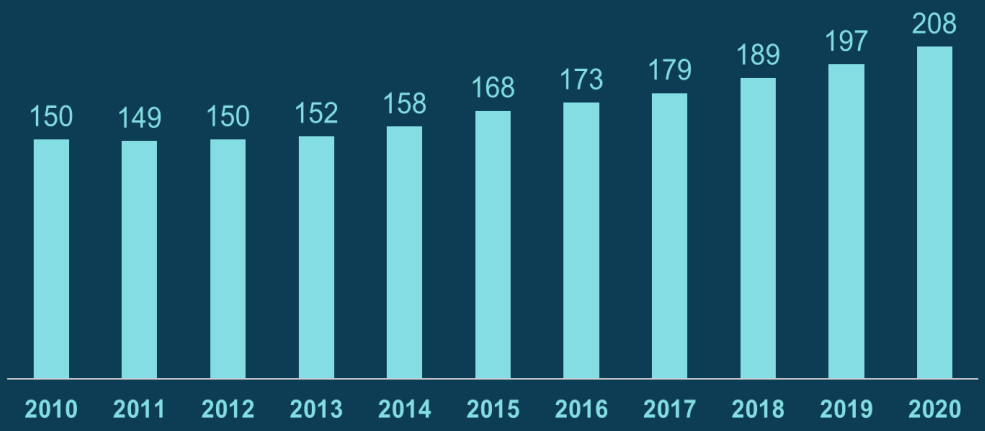
Kasper Ernest
Secretary General
Affordable Medicines Europe

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 update the facts around the parallel trade flows in Europe, first documented in 2018. We hope it will contribute to a sound discussion on 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 €

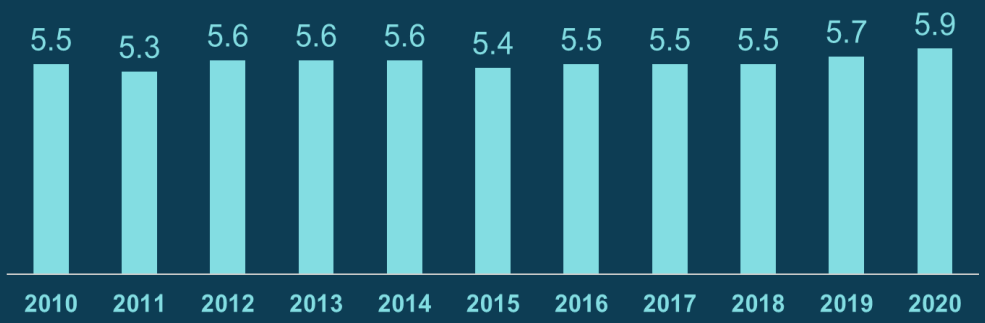


Source: EFPIA, as well as estimate for 2020 based on available data

Share of the total market in %

The parallel import market have remained more or less stable in the past decade, albeit with very moderate growth in 2019-2020. At the same time, the total medicines market in the EU has been growing much more rapidly, why the share of parallel imports fell to a record low 2.8% in 2020.

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 or the UK. 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) and the UK 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 covers a big majority of the total PI sales in the EEA countries and the UK (still in Single Market in 2020).

Affordable Medicines Europe conducted a survey among its membership that resulted in 67 submissions from 17 countries: Austria, Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Spain, Sweden and the UK. These markets cover almost the total value of PI sales in Europe[1]. Companies were asked about the original source country of the imports by country in % of value and their market share.

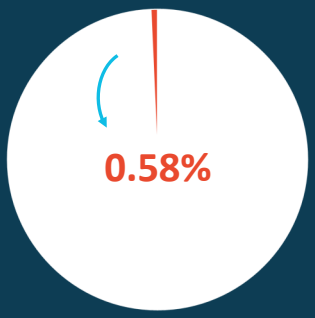
This report will first summarise the main trends found in the data, and then it will provide a country by country analysis of the results. ■

[1] Data from IQVIA

The majority of medicines in shortage are generic medicines. According to Medicines for Europe, 29% of pharmaceutical expenditure in Europe is on generic medicines. This translates to € 60.9 billion in 2020 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 € 5.9 billion in 2020 according to IQVIA—that is € 354 million. This means that parallel imports in the generic market is less than 0,6% of the total market.

Parallel trade in generics



METHODOLOGY

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 2020[2].
2. The market share of the company in the national PI industry in 2020.

The study is built on 67 submissions from the 17 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 sales[3]. 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, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Spain, Sweden and the UK. These cover almost the entire PI sales in Europe.

Definition of high-income countries

We consider high-income the twelve countries with the highest GDP per capita in 2020 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 completely[4].

$$\textit{European weighted average} = W_1C_1 + W_2C_2 + W_3C_3 + \ldots$$

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. In 2020, no extrapolation to account for remaining sales in Europe was necessary, as the study covers almost the entire market, unlike in 2018 when the coverage of data was lower.

$$\textit{national weighted average} = W_1C_1 + W_2C_2 + W_3C_3 + \ldots$$

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 used in order to calculate some of the variables[5]. ■

[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, where the data covered 32.6% of the market, and Cyprus, with 50% of the market, are the exceptions.
[4] Data from IQVIA.
[5] Data from Eurostat.

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. Since 2018, sourcing from high-income countries increased from 51% to 52%. 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 Europe 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/EEA country or the UK 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.

Results for total trade in value

The analysis revealed that 52.4% 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. the UK to Denmark or from Germany to Poland.

The same trend can be observed at the national level in 10 out of the 17 countries, where more

52%

of parallel imports come from high-income countries

Top 3 source/export countries in 2020:

1. **France**
2. **Germany**
3. **United Kingdom**

than 50% of the PI come from high-income Member States (Austria, Belgium, Denmark, Finland, Germany, Netherlands, Norway, Spain, Sweden and the UK).

It must be noted that in all the main European markets for PI products, i.e. those countries with a gross value of parallel imports over € 200 million, more than half of the imports are from the economies with a higher GDP per capita level. In the next chapter a separate overview of all 17 countries will be provided.

Results per capita

While the results in total volumes put France and Germany in front, unsurprisingly considering the size of their markets, an analysis was furthermore conducted to consider parallel exports per capita.

The average European export per capita was 16.7 euro. Both France, Germany and the UK exported less than average per capita despite being the largest exporters in total volume terms.

After Brexit, the proportion of PI products coming from the UK has decreased, in favour of especially Germany

In 2020, Sweden was the country with the highest proportion of its parallel imports originating from high-income countries: 60%.

The results also show that France, Germany and the UK are the three main sources of medicines in the EU/EEA plus the UK. Especially noteworthy, is Germany's jump from the 10th largest exporter in 2018, to the 2nd largest in 2020.

After Brexit, it is also noteworthy that only 8% of all European PI originates from the UK. **This share is down from 11% in 2018**. This number will, after the UK left the Single Market at the end of 2020, fall to zero.

However, neither France, Germany nor the UK are amongst the countries exporting most per capita (they rank 15th, 20th and 22nd respectively).

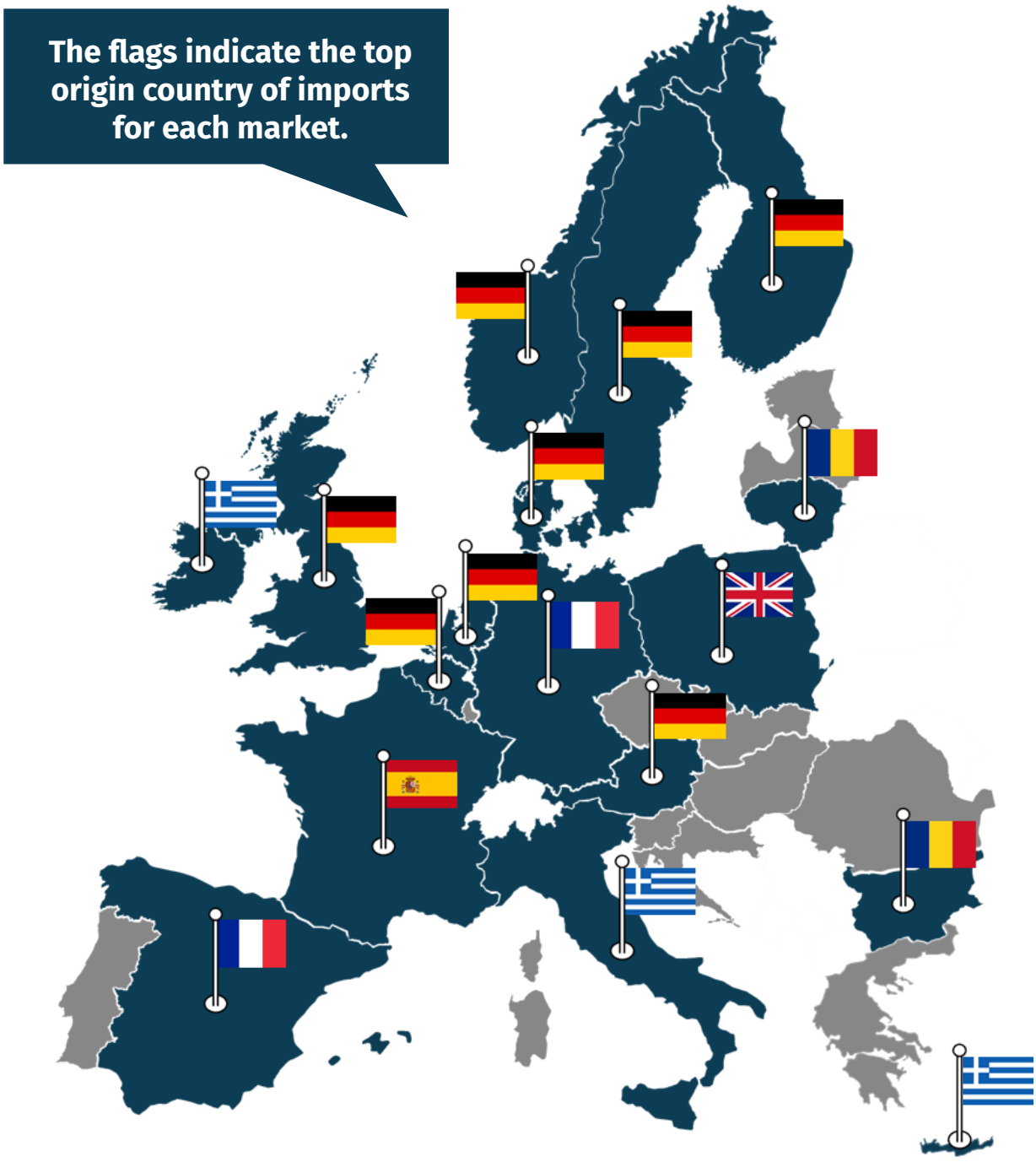
A number of countries often considered to be lower-priced exporting countries such as **Italy, Hungary, Poland, Spain, Estonia or Croatia export below or far below the European average.** In contrast, countries often perceived as high-priced countries such as Norway, Austria, the Netherlands and Belgium were above average.

The Netherlands and Austria are good examples of countries where both the imports and exports per capita are above the average. This means there are opportunities to benefit from PI for everyone, as excess medicines can help bring down prices in other countries, 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 58.8%**
- **Belgium 50.2%**
- **Denmark 57.5%**
- **Finland 59.0%**
- **Germany 51.9%**
- **Netherlands 57.5%**
- **Norway 57.3%**
- **Spain 51.2%**
- ***Sweden 60.1%***
- **UK 50.8%**

Main origin of parallel imports by country in € volumes



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.

Analysis: The origins of imports not destined for Germany

Germany is the country with the biggest parallel imports industry in Europe. 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 Europe are significantly influenced by the trends in Germany.

To control for this fact, an additional analysis excluding the German imports from the calculations of the origin of the trade flows was performed. 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 Europe (minus Germany) by a large margin, followed by France[6]. 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 and the UK.**

In fact, Germany is the top source of parallel imports in the four other biggest PI markets in Europe (UK, Netherlands, Denmark and Sweden), and in another four (Austria, Finland, Belgium and Norway). It is worth noting that **Germany's relevance as a source of PI has significantly increased after Brexit.**

Discussion

While most academic literature, media reports, and political statements reiterate that parallel trade is a concept whereby products flow from low-income to high-income countries in Europe 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 gives a clear picture of the true nature of the trade flows in the parallel distribution market in Europe. Now repeated in 2020, the 2018 findings have been confirmed: more than 50% of imports sold in the main PI markets 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 eight out of the seventeen countries featured in the study, including the four most relevant markets by sales turnover (besides the German).

The share of imports from Germany in those countries is the following:

- **Austria** 26.1%
- **Belgium** 14.3%
- **Denmark** 20.0%
- **Finland** 22.2%
- **Netherlands** 34.6%
- **Norway** 24.4%
- **Sweden** 25.6%
- **UK** 18.1%

In total, Germany is the main exporter for the remaining EU/EEA market, by a large margin, while France follow in 2nd place:

1. **Germany** 21.8%
2. **France** 13.6%

CONCLUSION

The evidence collected by Affordable Medicines Europe proves that more than half of the parallel imports of pharmaceuticals originate from 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 the east to the 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, Portugal or Bulgaria.

France, Germany, and the 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 the top source to eight of the 16 remaining 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 directly 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 European level.

COUNTRY OVERVIEW

GERMANY

The German market accounts for more than half of the total sales of parallel imported medicines in Europe, the most in the continent. Parallel imports have been a great source of savings for the national health system.

The value of PI sales sold in Germany has increased from €2.9 to €3.1 billion between 2018 and 2020[7]. It is also the 2nd largest importer per capita in Europe, behind Denmark. About 9% of the total medicines dispensed in pharmacies in Germany are parallel imports[8].

In 2018, the total savings (direct and indirect) were above €2.8bn which go directly to the German health insurers (Krankenkassen)[9]. Since July 2019, a new savings target of 2% has been put in place between the pharmacies and health insurers.

As in 2018, the majority of parallel imports in 2020 come from high-income countries: 51.9% of the total. France, the UK, and the Netherlands are the three main sources of PI in Germany.

Germany is also the main source country/exporter for the rest of the EU/EEA and the UK as a whole. Almost 22% of the total PI sales in there come from Germany.

In fact, Germany is the top source of PI medicines for half of the remaining countries (8 out of 16), including the 4 most relevant markets by value of PI sales: the UK, Denmark, the Netherlands and Sweden. ■

[7] Data from IQVIA.
[8] Data from EFPIA.
[9] Savings report 2020: https://bit.ly/3cF9Ocf.

Size of the import market:

€3.1bn

Share of the total EU market:

51.0%

Share of parallel imports from high-income countries:

51.9%

UNITED KINGDOM

The United Kingdom has the 2nd largest market for parallel imported medicines in the EU/EEA plus the UK. The UK is relevant for this study, because until 31st December 2020, the UK market was still part of the EU/EEA Single Market.

British parallel imports amounted to €865 million in 2020[10], which represents nearly 14.0% of total sales in Europe. The UK is the 8th largest importer per capita. Almost 9% of the medicines dispensed in pharmacies are parallel imported[11].

In the UK, prices of medicines are agreed between the UK government and industry by means of the renegotiation of the Pharmaceutical Pricing Review Scheme every five years. Parallel importers in the UK are able to offer the same original and licensed medicines to pharmacies and wholesalers at a discounted price, generating savings both for pharmacies themselves and the Government, which gets back part of the benefit via a 5% clawback. More savings are created by the increase of price competition as a consequence of the introduction of PI medicines in the market.

More than half of the UK imports, 50.8%, come from high-income countries, with Germany being the main source, followed by France. The UK is not only the 2nd biggest market for parallel imported pharmaceuticals, it is also the 3rd largest source for PI sales coming into Europe. As is the case for Germany, the UK proves that high income countries can benefit from parallel imports, but they also contribute with exports of medicines to other markets. ■

[10] Data from IQVIA.
[11] Data from EFPIA for 2019.

TOP SOURCES:

1. **Germany**
2. **France**
3. **Greece**

Size of the import market:

€865m

Share of the total EU market:

14.0%

Share of parallel imports from high-income countries:

50.8%

NETHERLANDS

The gross value of parallel imported medicines in the Netherlands amounted to roughly €641 million in 2020[12], which makes it the 3rd biggest market in Europe (the second at the EU level) with 10.4% of the total sales.

Parallel imports are an integrated part of the Dutch medicines supply chain. More or less half of the Dutch parallel imports are sold in pharmacies. In fact, around 7% of all medicines dispensed in Dutch pharmacies are parallel imports[13]. The other half of the Dutch parallel imports are sold to hospitals, where parallel imports are also a very important supply channel.

As in comparable markets, such as the Swedish, the Danish, and the German, savings from parallel imports in the Netherlands are considered to be significant. These include both direct savings based on price differences as well as indirect savings from the competitive pressure exerted on prices from parallel imports.

Almost 58% of the total parallel imports of medicines sold in the Netherlands come from high-income countries. Germany, France, and Italy are the three main sources. In fact, Germany is the source of more than 1/3 of Dutch parallel imports (34.6%). This makes the Netherlands the country most reliant on imports coming from Germany.

The Netherlands also rank above the European average both on parallel imports and exports per capita. Around 6% of the total PI sales in Europe are sourced in the Netherlands. ■

[12] Data from IQVIA.
[13] Data from EFPIA for 2019.

Size of the import market:

€641m

Share of the total EU market:

10.4%

Share of parallel imports from high-income countries:

57.5%

TOP SOURCES:

1. **Germany**
2. **France**
3. **Italy**

DENMARK

Denmark is the 4th 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 25% of all medicines dispensed in Danish pharmacies are parallel imports[14].

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

In 2019, 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 year[15].

In 2020, nearly 58% of the parallel imported medicines sold in Denmark originated from the other 11 European countries with the highest level of GDP per capita. Actually, the top three sources are included in this group: Germany, France, and the UK.

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. ■

[14] Data from EFPIA for 2019.
[15] 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:

6.5%

Share of parallel imports from high-income countries:

57.5%

SWEDEN

The value of parallel imported medicines sales in Sweden has decreased from about €400 million in 2018 to just above €350 million in 2020[16], which equates to 5.7% of total sales in Europe. It is still the 5th largest market in Europe, and the 4th per capita.

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 almost 10% [17]. This is the 2nd highest share (with the Netherlands) in Europe after Denmark.

Savings from parallel imports are reaped by pharmacies and hospital counties. In 2018, savings from parallel imports amounted to €235 million in the pharmacies alone[18]. In fact, when competition from parallel imports is introduced for a given product, it leads to a drop of the originators revenue with 17% on average.

Sweden is the country with the biggest proportion of PI medicines coming from countries with a high level of GDP per capita. Just above 60% of parallel imports are sourced among the high-income countries. The top three sources are also considered high-income countries: 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 if barriers were removed. ■

[16] Data from IQVIA.
[17] Data from EFPIA for 2019.
[18] Savings report 2020: https://bit.ly/3cF9Ocf.

Size of the import market:

€351m

Share of the total EU market:

5.7%

Share of parallel imports from high-income countries:

60.1%

TOP SOURCES:

1. **Germany**
2. **France**
3. **UK**

IRELAND

Ireland leads a second group of countries whose sales of parallel imported medicines amount to less than €200 million.

In 2020, parallel import sales in Ireland amounted to €149 million[19], which is equal to around 2.4% of the European total. However, in terms of parallel imports per capita, Ireland comes 5th in Europe.

Although its size is considerably smaller than the previous presented markets, it is steadily growing, as it registers a 14% increase of gross value since 2018.

Parallel imports are an integrated part of the Irish medicines supply chain. The share of parallel imports in the pharmacy sales market is at 6%[20].

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, France, and the Netherlands. Ireland has, as one of the few markets, less than half of the parallel imported medicines coming from high-income countries, with about only 33%.

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.

On the exports' side, Ireland is slightly above the European average per capita. ■

[19] Data from IQVIA.
[20] Data from EFPIA for 2019.

Size of the import market:

€149m

Share of the total EU market:

2.4%

Share of parallel imports from high-income countries:

32.5%

AUSTRIA

Austria is one of the fastest growing markets for parallel imported medicines in Europe. It has developed from €60 million in sales in 2018 to €148 million in 2020[21], which makes it the 7th largest market in Europe with 2.4% of total sales. Austria is also above the average in parallel exports per capita.

The 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.

Whether the recent growth rates of the industry can be maintained remains to be seen and it will depend to a great extent on the regulatory environment and restrictions.

59% of the parallel imports sold in Austria come from high-income countries, with Germany, France, and Romania (not included in the group of high-income countries) as the three main sources, followed by the UK and the Netherlands as 4th and 5th respectively, which are obviously also in the high-income range. More than 26% of the imports are now sourced in Germany, more than double compared to 2018. ■

[21] Data from IQVIA.

Size of the import market:

€148m

Share of the total EU market:

2.4%

Share of parallel imports from high-income countries:

58.8%

TOP SOURCES:

1. **Germany**
2. **France**
3. **Romania**

FINLAND

In Finland, the gross value of sales of parallel imports has grown significantly in recent years. It went from €80 million in 2018 to €110 million in 2020[22].

This corresponds to 1.8% of the total sales of PI in Europe, and makes Finland the 8th largest importer in Europe. Sensible incentives for parallel imports are one of the reasons for this positive evolution.

At the same time, Finland's level of parallel exports is relatively low, both in value and in per capita terms. This is primarily due to the high prices of specialty medicines and the structure of the Finish medicines supply chain.

Finland has the 2nd largest proportion of PI medicines originating from high-income countries, with 59% (together with Austria). The 3 main sources are also countries with a high GDP per capita: Germany, France, and the UK.

Savings from parallel imports in Finland from 2016-2020 were quantified by Copenhagen Economics recently. The study shows, that despite the relative small size of the Finnish PI market, savings in Finland amounted to €41 million. This corresponds to an average saving on PI medicines of approximately 8%. It is estimated, that there is further potential for growth in and higher savings from PI in Finland[23].

In Finland, PI accounted for a 2.9% market share in the pharmacy market and a 6.4% share in the hospital sector. This, should be seen in light of the fact, that the pharmacy market is in general 3-4 times larger than the hospital market. ■

[22] Data from IQVIA.
[23] CE study 2021: https://bit.ly/3juTh17.

TOP SOURCES:

1. **Germany**
2. **France**
3. **UK**

Size of the import market:

€110m

Share of the total EU market:

1.8%

Share of parallel imports from high-income countries:

59.0%

ITALY

Italy is the Mediterranean country with the largest market for parallel imports, and the 9th largest at the European level. Sales amounted to €103 million in 2020[24], almost €20 million less than in 2018.

After a rapid growth in the past, the market seems to have stagnated in the last couple of years. This is mainly due to regulatory barriers, such us the lack of reimbursement for parallel imports.

The Italian parallel import sector estimates 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)[25].

Greece was the main source of imports in Italy, followed by the UK and Germany. Compared to 2018, this is a significant shift in sources, especially as France is now out of the top 5, whereas it was the largest source in 2018. However, in total 44.3% of the imports still come from high-income countries.

Italy is way below the average when it comes to exports per capita, where it is only the 23rd largest exporter. ■

[24] Data from IQVIA.
[25] Savings report 2020: https://bit.ly/3cF9Ocf.

Size of the import market:

€103m

Share of the total EU market:

1.7%

Share of parallel imports from high-income countries:

44.3%

POLAND

The value of the Polish market of parallel imports amounted to €93 million in 2020[26], which is down from € 100 million in 2018. A significant decrease, which is primarily caused by a worsened incentive structure for PI in Poland. With growth in other markets, it also means that Poland has taken several jumps back in terms of its place in the total European market.

However, considering that the Polish parallel import market is among the youngest in the EU (parallel trade has only been possible since Poland joined the EU), it has developed rather quickly, and today it is 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)[27].

However, the Polish government 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.

The main source of imports in Poland is the UK (up from 3rd place in 2018). Romania and Greece complete the top 3. A third of the parallel imports come from the group of countries with the highest GDP per capita level, more or less the same as in 2018. Poland is not among the main parallel exporters in Europe, not in absolute value nor in per capita terms. ■

[26] Data from IQVIA.
[27] Polish savings report 2020: https://bit.ly/3cF9Ocf.

TOP SOURCES:

1. **UK**
2. **Romania**
3. **Greece**

Size of the import market:

€93m

Share of the total EU market:

1.5%

Share of parallel imports from high-income countries:

33.1%

BELGIUM

The Belgian market for parallel imported medicines is also experiencing a rapid growth in the recent years. In 2018 total sales of PI products amounted to €60 million; and in 2020 they have grown to €88 million[28] (1.4% of the total sales of PI in Europe), an increase of almost 50%.

However, the evolution of the PI industry is being hindered by 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.

50% of the parallel imported medicines sold in the Belgian market come from high-income countries. Germany, the UK, and Poland (not counted as a high-income country) are in the top 3 in 2020.

Albeit Brexit not having taken practical effect in the market in 2020, Belgian importers seem to have already readjusted their sourcing patterns, as the UK fell from a clear 1st position, with 30% sourced in the UK, to now being 2nd, at only 13%.

Belgium is also above the average in exports per capita, but around the median when it comes to parallel imports.

If regulatory conditions allow for a continuation of the industry's growth, the balance between parallel exports and imports is expected to even out more in the coming years. ■

[28] Data from IQVIA.

Size of the import market:

€88m

Share of the total EU market:

1.4%

Share of parallel imports from high-income countries:

50.2%

TOP SOURCES:

1. **Germany**
2. **UK**
3. **Poland**

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).

Norway is the first of a group of countries with a smaller market for parallel imported medicines (below €50 million euro).

Sales in Norway have been steadily decreasing in recent years. They have gone from about €50 million in 2018 to €38 million in 2020[29]. This makes it the smallest Nordic market for PI by far.

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. This could easily be changed, by creating a better parallel import framework, that would ensure savings to the healthcare payers.

57.3% of the imports come from the countries with a higher level of GDP per capita. Germany is the main source by a margin (having increased more than 10% since 2018), followed by France and Romania.

Norway is not one of the main sources of imports for the rest of the continent, but it ranks above the average in exports per capita, where it was 1st in 2018 it is 7th in 2020.

While acknowledging that parallel export is not a contributor to shortages in Norway, the Norwegian government has introduced unfair legislation to restrict exports of medicines in shortage. ■

[29] Data from IQVIA.

TOP SOURCES:

1. **Germany**
2. **France**
3. **Romania**

Size of the import market:

€38m

Share of the total EU market:

0.6%

Share of parallel imports from high-income countries:

57.3%

SPAIN

In 2020, the sales of parallel imported medicines in Spain amounted to €13 million[30], which is about the same level than in 2018.

More than half of the imports come from high-income countries, as it also happened in 2020. The top 3 sources of PI products in Spain is composed of other Mediterranean countries: France, Italy, and Greece. France is the largest by a large margin, being the source of 37% of all PI in Spain in 2020.

Considering the small size of the Spanish parallel import market, individual medicinal products play a significant role in the trade flow pattern for the market. Therefore, fluctuations in the Spanish market are dependent on the development of prices for just a few individual medicinal products. It is expected that there is a good potential for PI growth in Spain, but it requires a better parallel import framework than the one currently in place.

Despite the fact that many consider Spain to be an eminently exporting market, it is considerably below the European average in exports per capita. In fact, Spain is below countries like Germany, the Netherlands, and the UK, both in relative and absolute terms.

Spain has export restriction legislation in place to ensure that medicines in shortage are not parallel exported. This system is generally well managed and exports are not considered a main cause of shortages. ■

[30] Data from IQVIA.

Size of the import market:

€13m

Share of the total EU market:

0.2%

Share of parallel imports from high-income countries:

51.2%

FRANCE

The sales of parallel imported medicines in France amounted to €11 million in 2020[30], a 25% decrease compared to 2018.

This represents only about 0.2% of the total sales of PI in Europe. This fact, along with France's large population, makes it one of the countries with the lowest parallel imports per capita. Despite being the main source of parallel imports in Europe, France is well below the average of exports per capita (15th).

It is noteworthy that, as France is the top 1 country for Spain's parallel imports, Spain is main source for its neighbour, with a significant part of the total share.

The French market could grow significantly if the parallel import framework would become compliant with EU law. Currently France is not reimbursing PI products imported into France using the EMA procedures (centrally authorised).

According to the French national medicines agency, the ANSM, parallel exports are not among the main causes of medicine 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 identified[29].

France has legal provisions to ban parallel exports for individual medicines in shortage. ■

[30] Data from IQVIA.

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

Size of the import market:

€11m

Share of the total EU market:

0.2%

Share of parallel imports from high-income countries:

10.5%

LITHUANIA

For the first time, Lithuania has been included in a trade flow study. This is due to the rapid growth in the Lithuanian parallel import market, which makes it possible to quantify better the development. Lithuania is leading the way for PI in the Baltics, which is foreseen to become a major part of the supply of medicines in these countries. In Latvia, for example, PI already account for around 2% of the medicines market.

Lithuania has small and relatively new parallel imports industry, however, with a significant number of players on the market.

In 2020 sales amounted to €8 million[33]. Although the figure is low compared to most countries, it still ranks above others like Poland or Italy in imports per capita.

It is expected that the Lithuanian market has a good growth potential in the coming years, and that sourcing will diversify further.

Currently, Romania, Poland, and Bulgaria are the main sources of parallel imports in Lithuania, but with fairly even distribution among many countries, including some of the high-income countries.

About a quarter of the imports come from high-income countries, of which the more important share comes from Belgium.

Lithuania is not among the main parallel exporters in Europe, but it is above the average in per capita terms. ■

[33] Data from IQVIA.

Size of the import market:

€8m

Share of the total EU market:

0.1%

Share of parallel imports from high-income countries:

25.6%

TOP SOURCES:

1. **Romania**
2. **Poland**
3. **Bulgaria**

BULGARIA

Bulgaria's parallel import market is among the smallest in Europe, with a turnover of €4 million. It has remained almost unchanged since 2018, despite the promising development in previous years. In spite of its small scale in absolute terms, the value of parallel import sales per capita surpasses other countries such as Spain or France.

Romania, Poland and Hungary were the main sources of imports in 2020. In this case, a low percentage of them comes from high-income countries.

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

Furthermore, PI can be used as a powerful tool to alleviate shortages in the country.

The Bulgarian Association for Medicines Parallel Trade Development (BAMPTD) has promoted initiatives to mitigate supply problems via parallel imports of the medicines that cannot be found in the market[34].

In Bulgaria parallel exports are strictly regulated, and products in shortage will be restricted from being exported until normal supplies are restored. Hence, exports do not contribute to shortages. ■

[34] Voinova, 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:

10%

CYPRUS

For the first time, Cyprus has been included in a trade flow study, as in the past there was not sufficient data to include it.

Cyprus has the smallest parallel import market of the sample, with just about one million euro in sales turnover. They are mostly sourced in its neighbour country Greece, due to the fact that re-packaging needs are extremely limited, since they are already in the Greek language.

Cyprus is challenged when it comes to import from other markets than Greece, since it would require repackaging of the products. However, due to the extremely small size of the market, re-packaging is not economically viable.

Therefore Cypriot parallel importers will typically work much more with other types of import authorisations than specifically parallel import authorisation, when trying to cover the needs of patients in Cyprus. This is not least when products are in shortage or not supplied at all by the pharmaceutical industry. Hence, parallel importers have an increasingly important role in the supply of medicines in Cyprus.

Cypriot parallel exports are almost negligible in absolute terms, and they are also way below the European average in per capita terms. In general Cyprus have very low stock levels, and therefore there is very limited quantities available for exports. Considering the size of the market, this is not foreseen to change.

Parallel trade is still a developing industry, as very few companies operate in the market, but as the demand for specialised imports is increasing, this may change.

Size of the import market:

€1m

Share of the total EU market:

0.02%

Share of parallel imports from high-income countries:

0%

TOP SOURCES:

1. Greece

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 and the UK. 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 the UK, 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.