

WORKING IN PARALLEL FOR A BETTER DEAL



# TRADE FLOWS OF PARALLELIMPORTED MEDICINES2023

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

March 2024

Title: Study of the trade flows of parallel imported medicines in Europe Authors: Esco Agiuar, Matteo Poidomani, Kasper Ernest Editor: Matteo Poidomani Publisher: Affordable Medicines Europe

- Rue des Deux Églises 26, 1000 Brussels
- info@affordablemedicines.eu
- +32 491 255 611
- www.affordablemedicines.eu

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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.

Our members also increasingly provide access to medicines not launched by manufacturers in especially smaller Member States. Without the existence of viable parallel import sector, providing that access for the most disadvantaged Member States and patients would not be possible.

Over the last few years, we have witnessed a fresh surge in protectionist measures from EU Member States, resulting in the implementation of new export restrictions. We have even witnessed an increase in cases, where restrictions on exports have led to excess supplies being destroyed in the export market due to a lack of demand, while the product was in shortage in another Member State. We should not accept this ultimate failure of the EU's Single Market.





Kasper Ernest Secretary General Affordable Medicines Europe

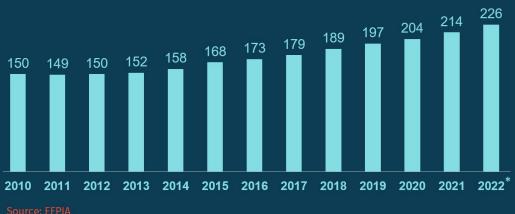
As witnessed during the COVID-19 crisis, restricting free movement of goods will decrease access to medicines. On the contrary, keeping parallel imports available to all countries, while assuring exports are never causing shortages, leads to the healthy parallel trade eco-system we advocate to nurture and maintain; a system which is currently under attack.

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 and then in 2020. This year, we have gathered data for both 2022 and 2023. 2022 marked the first year where the UK is no longer part of the EU Single Market.

With the UK's departure, Italy has now become the next in line to join the group of 12 highincome countries, that is relevant for this analysis. We hope this Study will contribute to a sound discussion on shortages and how all stakeholders in the medicines supply chain can contribute in alleviating them.

mu/ min Kasper Ernest

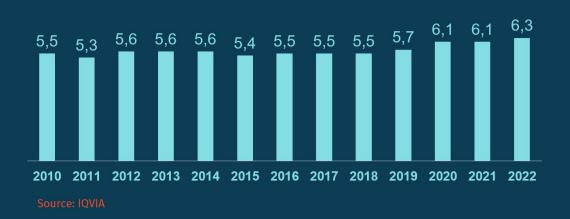
Secretary General



### Turnover EU medicines market in billion €

Source: EFPIA





# Turnover of EU parallel import in billion €



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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) 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.



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, which is now at its third edition, 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. For the first time, this survey does not include the UK, which is no longer part of the EU Single Market since 1 January 2021 due to Brexit. The UK has therefore also been replaced by Italy in the group of highincome countries. 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.

Affordable Medicines Europe conducted a survey among its membership that resulted in 73 submissions from 17 countries: Austria, Belgium, Bulgaria, Cyprus, Denmark, Finland, Estonia, France, Germany, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Spain and Sweden. These markets cover almost the total value of PI sales in Europe<sup>1</sup>. Companies were asked about the original source country of the imports by country in % of value and their market share.

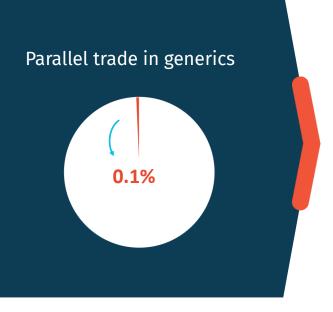
This report will first summarise the main trends found in the data, and then it will provide a country by country analysis of the results.

<sup>1</sup> Data from IQVIA

# The majority of medicines in shortage are generic medicines.

According to IQVIA, 8.2 billion packs of generic medicines are sold in the EU every year. In value this is about  $\in$  30 billion of yearly sales.

According to IQVIA, out of the 8.2 billion packs sold in Europe, approximate 8 million are parallel traded. **That is less than 0.1% of all packs sold in the EU!** These parallel traded packs have a value of about € 180 million, thus accounting for around 0.6% of the generic market in value.



**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 2022 and 2023 respectively<sup>2</sup>.
- The market share of the company in the 2. national PI industry in 2022 and 2023.

The study is built on 73 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 80% of the total national PI sales<sup>3</sup>. In most cases, there were data available to account for more than 95% of the total PI sales.

The countries included in the study are Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Spain and Sweden. These cover almost the entire PI sales in the EU.



- Denmark
- Sweden 0
- Belgium
- France **Netherlands** 
  - Italy

## 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<sup>4</sup>.

> *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

 $c_i$  = 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  $= W_1 C_1 + W_2 C_2 + W_3 C_3 + \dots$  $w_i$  = market share of company i

 $c_i$  = 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 variables⁵. ■

<sup>&</sup>lt;sup>2</sup> It is a legal obligation for all parallel importers to know the exact origin country of all the products they import. Most data collection companies only gather trade data, which indicate where a product was bought - not its origin. This makes the data used in this study unique, and gives a true picture of the country where the products was placed by the manufacturer/MAH.

<sup>&</sup>lt;sup>3</sup> Poland, where the data covered 32.6% of the market, and Cyprus, with 50% of the market, are the exceptions.

<sup>&</sup>lt;sup>4</sup> Data from IQVIA. <sup>5</sup> 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 2020, sourcing from high-income countries increased from 52% to 56% in both 2022 and 2023. The distribution among northern, southern and eastern countries is very homogeneous in the top 10 origin countries from which parallel imports come. France and Germany are still the two top exporters.

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 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 56% of the parallel imports in Europe in terms of euro value originate from high-income countries. That may be medicines going from e.g. Germany to Poland.

The same trend can be observed at the national level in 9 out of the 17 countries, where more than 50% of the PI come from high-income countries (Austria, Belgium, Denmark, Finland, Germany, Netherlands, Norway, Spain and Sweden).

# 56%

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



Top source/exporters in 2022 and 2023:

- 1. France
- 2. Germany

Furthermore, among the countries in the highincome group, only Ireland (49%), Italy (40%) and France (14%) had less than half of the imports coming from the other economies with a higher GDP per capita level. In the next chapter a separate overview of all 17 countries will be provided.

In 2022, the Netherlands was the country with the highest proportion of its parallel imports originating from high-income countries: 67%! In 2023 Sweden took first place with 65%, while the Netherlands came in second with 64%.

#### 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 19 euro per year. Both France and Germany exported less than average per capita despite being the largest exporters in total volume terms.

# After Brexit, parallel imports from the UK is no longer possible, whereas the UK used to be the 3<sup>rd</sup> largest exporter

#### The results also show that France and Germany continue to be the two main sources of medicines in the EU/EEA also after Brexit.

However, neither France nor Germany are amongst the countries exporting most per capita (they rank 15<sup>th</sup> and 21<sup>st</sup> respectively) in 2023.

After Brexit, and with the UK leaving the Single Market at the end of 2020, the share of PI originating in the UK is now equal to zero. In 2020 the UK was the 3<sup>rd</sup> largest parallel exporter at 8% of all parallel exports, and thus Brexit was a big hit for the EU parallel import market.

The loss of the UK as a source country has been fairly evenly distributed among the remaining EU Member States. No Member State has increased more than 2% from 2020 to 2022. A number of countries often considered to be lower-priced exporting countries, such as **Estonia**, **Hungary**, **Poland**, **Portugal or Croatia**, **export below or far below the European average**. In contrast, countries often perceived as highpriced countries such as Norway, Austria, the Netherlands and Belgium were above average. In fact, Norway is in 2023 back as the number one exporter per capita.

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 (% in 2023)

- Austria 61.5%
- Belgium 53.1%
- Denmark 61.4%
- Finland 62.9%
- Germany 55.1%

- Netherlands 63.6%
  - Norway 59.3%
- Spain 59.0%
- Sweden 65.0%

# Main origin of parallel imports by country in € value



The countries that participated in the study are coloured in blue. The flags placed in each country indicate the main source for that countries parallel import market. I.e. Germany is the largest exporter/source to the Dutch parallel import market, and France the mail source for the Italian parallel import market. This map indicate the 2022 results.

# Analysis: The origins of imports not destined for Germany

Germany is the country with the biggest parallel imports industry in Europe. Almost 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 by a large margin, followed by France<sup>6</sup>. 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 the six other biggest PI markets in Europe (Netherlands, Denmark, Sweden, Austria Ireland and Belgium), and in another two traditional markets (Finland and Norway). It is worth noting that **Germany's relevance as a source of PI has significantly increased after Brexit from 21.8% to 26.8%.** 

#### 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 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 for the third time with 2022 and 2023 data, the 2020 and 2018 findings have been confirmed: more than 50% of imports sold in the main PI markets originate from high-income countries.

<sup>6</sup> 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 market).



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

•	Austria	27.6%
•	Belgium	24.6%

•	Denmark	21.0%
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- Finland 23.6%
- Netherlands 46.0%
- Norway 22.3%
- Sweden 24.7%
- Ireland 20.2%



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

1.	Germany	<b>26.8%</b>
2.	France	13.4%

# 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.

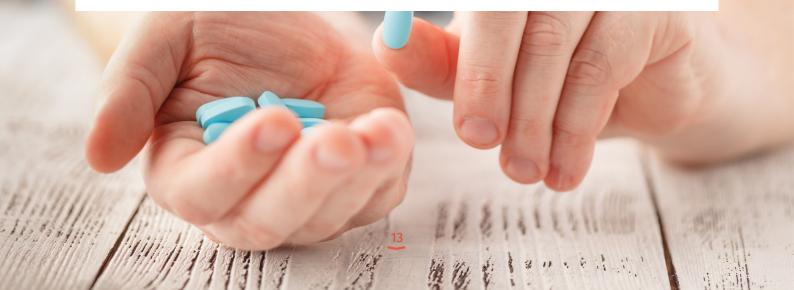
France and Germany are the main source countries at the European level, and Germany is the main source for the rest of Europe if German imports are excluded from the calculations. Germany is the top source to eight of the 16 remaining countries in the study.

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 many individual 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 for price competition across all country borders. 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 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

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GERMANY

The German market accounts for almost 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 decreased from  $\in 3.1$  to  $\notin 2.9$  billion between 2020 and 2022<sup>7</sup>. It is also the 3<sup>rd</sup> largest importer per capita in Europe, behind Denmark and Sweden. About 7% of the total medicines dispensed in pharmacies in Germany are parallel imports<sup>8</sup>.

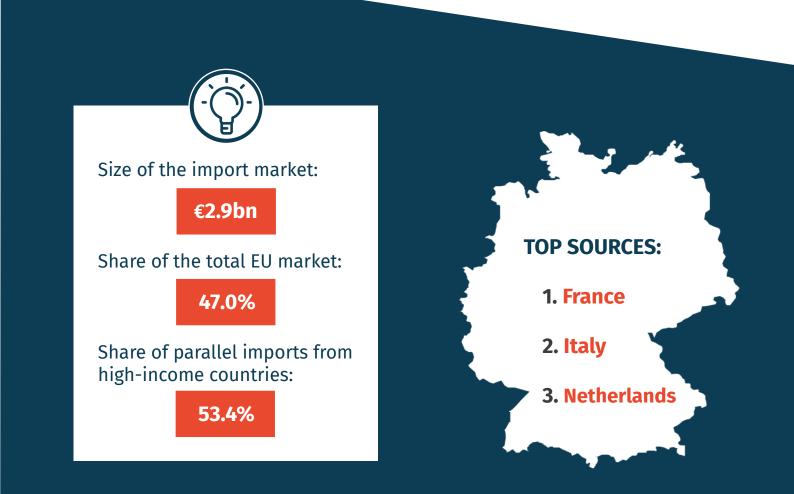
In 2018, the total savings (direct and indirect) were above €2.8bn which go directly to the German health insurers (Krankenkassen)<sup>9</sup>. Since July 2019, a new savings target of 2% has been put in place between the pharmacies and health insurers.

53.4% of parallel imports in 2022 come from high-income countries, with France (20.7%) being the main source of PI in Germany.

Germany is also the main source country/ exporter for the rest of the EU/EEA. Almost 27% of the total PI sales in the rest of the EU/EEA 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 six most relevant markets by value of PI sales: the Netherlands, Denmark, Sweden, Austria, Ireland and Belgium.

<sup>9</sup>Savings report 2020: <u>https://bit.ly/3cF9Ocf</u>.



<sup>&</sup>lt;sup>7</sup> Data from IQVIA.

<sup>&</sup>lt;sup>8</sup> Data from EFPIA, 2023.

DENMARK

Denmark is the 3<sup>rd</sup> largest parallel import market in Europe. However, per capita, Denmark is by far the largest parallel importer.

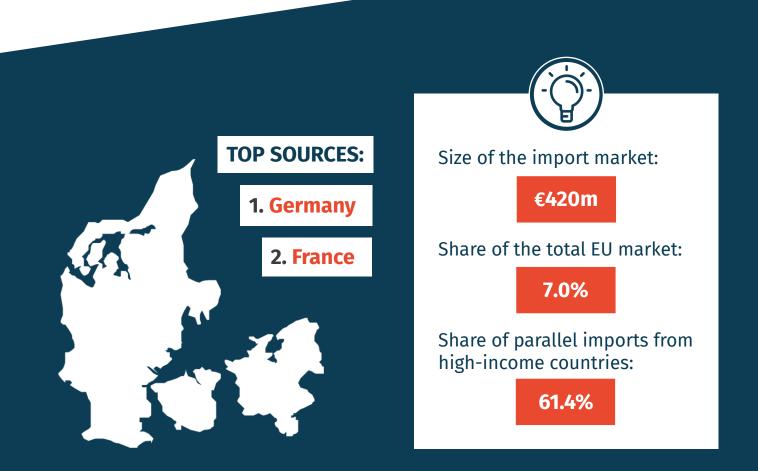
The Danish pharmacy tender system is the primary cause of the success of parallel imports in Denmark. With transparent national 14-day tenders for all pharmacy supply, parallel importers can take full advantage of the competitive pressure from parallel trade. As a result, around 30.4% of all medicines dispensed in Danish pharmacies are parallel imports<sup>10</sup>.

Parallel imports also have a noticeable share of the hospital market at around 9%<sup>11</sup>. This is partially explained by the high prices of specialty medicines in Denmark.

Savings from parallel imports in Denmark go to the State at the regional level, since the Regions are responsible for the provision of healthcare in Denmark, including medicines. In 2022, Copenhagen Economics estimated that savings from parallel imports in 2021 amounted to €100 million<sup>12</sup>. This was a significant increase compared to 2018.

In 2023, 61.4% of the parallel imported medicines sold in Denmark originated from the other 11 European countries with the highest level of GDP per capita. This is a significant increase from both 2018 and 2020.

As with most other markets, the top two source countries are Germany and France. 21.1% of all Danish parallel imports come from Germany. France is number two with 14.5%. The remaining countries are fairly evenly distributed from 8% and below.



<sup>&</sup>lt;sup>10</sup> Data from EFPIA for 2023.

<sup>&</sup>lt;sup>11</sup>Copenhagen Economics 2022: <u>https://rb.gy/r5xk09</u>

<sup>&</sup>lt;sup>12</sup> Idem.

NETHERLANDS

The sales of parallel imported medicines in the Netherlands amounted to roughly €510 million in 2022, which makes it the 2<sup>nd</sup> biggest market in Europe with 8% of the total sales<sup>13</sup>.

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 14.0% of all medicines dispensed in Dutch pharmacies are parallel imports<sup>14</sup>. The other half of the Dutch parallel imports are sold to hospitals, where parallel imports are also a very important supply channel.

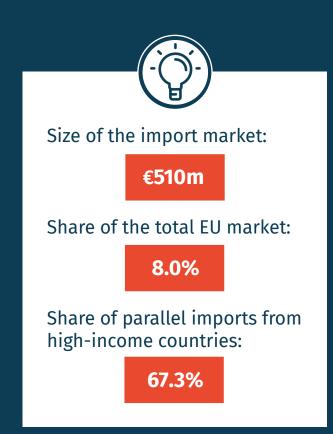
As in comparable markets, such as the Swedish, the Danish and the German, savings from parallel imports in the Netherlands are considered to be significant. These include both direct savings based on price differences as well as indirect savings from the competitive pressure exerted on prices from parallel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

The Netherlands is the country with the biggest proportion of PI medicines coming from countries with a high level of GDP per capita. Just above 67% of parallel imports are sourced among the high-income countries. Germany and France are the two main sources. In fact, Germany is the source of more almost half of Dutch parallel imports (46.0%). This makes the Netherlands the country most reliant on imports coming from Germany.

The Netherlands also ranks above the European average both on parallel imports and exports per capita. Around 5.9% of the total PI sales in Europe are sourced in the Netherlands.

<sup>13</sup> Data from IQVIA.

<sup>14</sup> Data from EFPIA for 2023.





**ESTONIA** 

Estonia is one of the smallest but also newest and fastest developing markets for parallel imports in Europe. From 2021 to 2023, the Estonian parallel import market grew by an astonishing 165%.<sup>15</sup> It should be noted, that Estonia came from a very low starting point in 2021.

The market share of parallel imports in Estonia is becoming more significant. Estimates for the pharmacy market are around 2-5%.

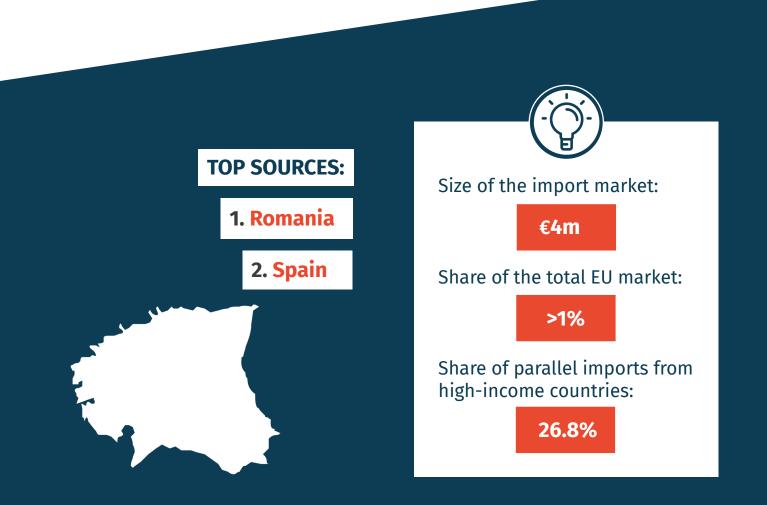
In Estonia, the parallel trade sector has a wider presence than what would be considered traditional parallel import. To an increasing extent, parallel imports are using their expertise, knowledge and existing sales staff to ensure access to products that are not made available in the market by the manufacturer.

Often this kind of business activity can be difficult to quantify for the existing data collections schemes, and therefore the actual importance of parallel import actors' presence in Estonia is most likely underestimated in the market size and market share data.

Estonia is not a significant export country. In fact, per capita, Estonia is below the European average.

Considering the rapid growth of the Estonian import market, it is the first time Estonia is included in the Trade Flow Study. In terms of parallel import, Estonia has seen significant changes in which countries is its main sources between 2022 and 2023. In 2022, Romania, Spain and Croatia topped the list, while in 2023 Poland was the biggest source, with Romania and Germany in 2<sup>nd</sup> and 3<sup>rd</sup> place.

<sup>&</sup>lt;sup>15</sup> Data provided by IQVIA.



SWEDEN

The value of parallel imported medicines sales in Sweden has slightly increased from about  $\in$ 350 million in 2020 to  $\in$ 380 million in 2022<sup>16</sup>, which equates to 6% of total sales in Europe. It is still the 4<sup>th</sup> largest market in Europe, and the 2<sup>nd</sup> 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, the share of parallel imports in the pharmacy sales market is higher at almost 12.4%<sup>17</sup>. This is the 3<sup>rd</sup> highest share in Europe after Denmark and the Netherlands.

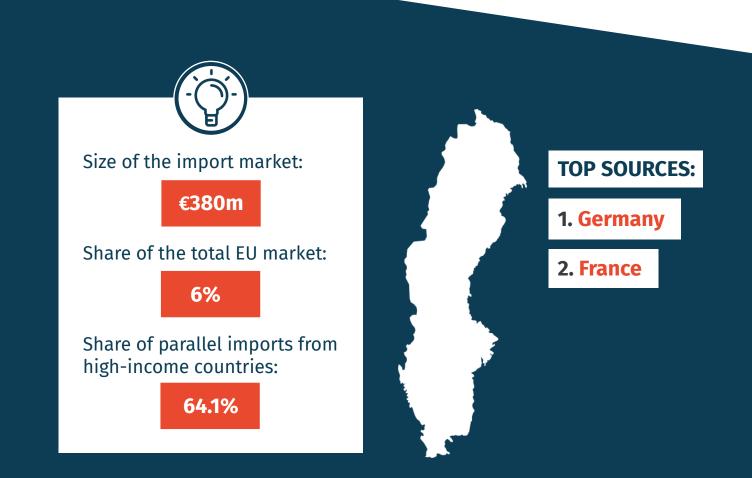
Savings from parallel imports are reaped by pharmacies and hospital counties. In 2018, savings from parallel imports amounted to €235

million in the pharmacies alone<sup>18</sup>. 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 has the 2<sup>nd</sup> largest proportion of PI medicines originating from high-income countries, with 64.1%. The top two sources are also considered high-income countries: Germany and France. Together these two countries account for more than 41% of all the export into the Swedish parallel import market.

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.

- $^{\rm 17}$  Data from EFPIA for 2023.
- <sup>18</sup> Savings report 2020: <u>https://bit.ly/3cF9Ocf</u>.



<sup>&</sup>lt;sup>16</sup> Data from IQVIA.

IRELAND

Ireland is in the group of countries whose sales of parallel imported medicines amount to less than €200 million, but is a mature and fairly developed market.

In 2022, parallel import sales in Ireland amounted to €140 million<sup>19</sup>, which is equal to around 2.2% of the European total. However, in terms of parallel imports per capita, Ireland comes 5<sup>th</sup> in Europe.

Since 2020, Ireland registered a slight decrease of around 6% in the size of its parallel import market. This is primarily due to continued hindrances in connection with reimbursement.

Parallel imports are an integrated part of the Irish medicines supply chain. The share of parallel imports in the pharmacy sales market is at  $6.2\%^{20}$ .

Savings in Ireland are considered to be signifi-

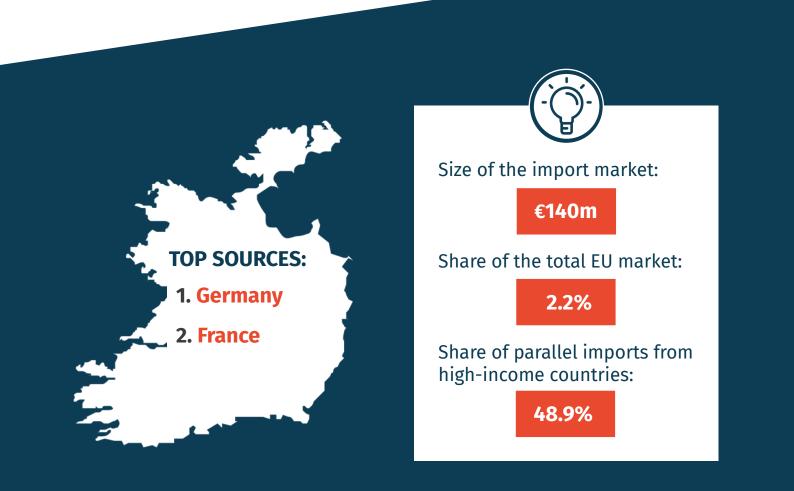
cant following a 8.5% discount agreement on all PI turnover paid back to the Health Service.

The main sources of parallel imported medicines in Ireland are Germany and France. In 2022, 49% of the parallel imported medicines came from high-income countries, and this value increased significantly from 2020, when only 33% of the products were coming to Ireland from high-income countries.

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.

<sup>19</sup> Data from IQVIA.

<sup>20</sup> Data from EFPIA for 2023.



## AUSTRIA

Austria is one of the fastest growing markets for parallel imported medicines in Europe. It has developed from €148 million in sales in 2020 to €190 million in 2022<sup>21</sup>, which makes it the 5<sup>th</sup> largest market in Europe with 3% of total sales.

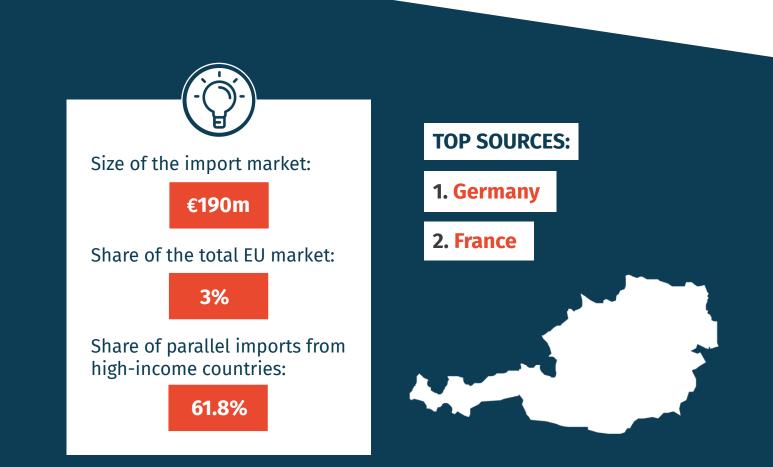
The growth in parallel imports in Austria is primarily found in the hospital sector. Hospital tenders are often smaller and for shorter than usual periods. These are beneficial conditions for parallel imports, whereby competition is significantly spurred.

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.

Almost 62% of the parallel imports sold in Austria come from high-income countries, with Germany and France, as the two main sources. Around 28% of the imports are now sourced in Germany, more than double compared to 2018. France is in second place, and together with Germany makes up 42% of all parallel imports.

Austria is also above the average in parallel exports per capita, at 7<sup>th</sup> place in Europe, while in total exports Austria is in 10<sup>th</sup> place. Austria is one of the countries that is moving towards an equilibrium between imports and exports.

<sup>21</sup> Data from IQVIA.



FINLAND

In Finland, the gross value of sales of parallel imports went from  $\notin$ 110 million in 2020<sup>22</sup> to  $\notin$ 90 million in 2022.

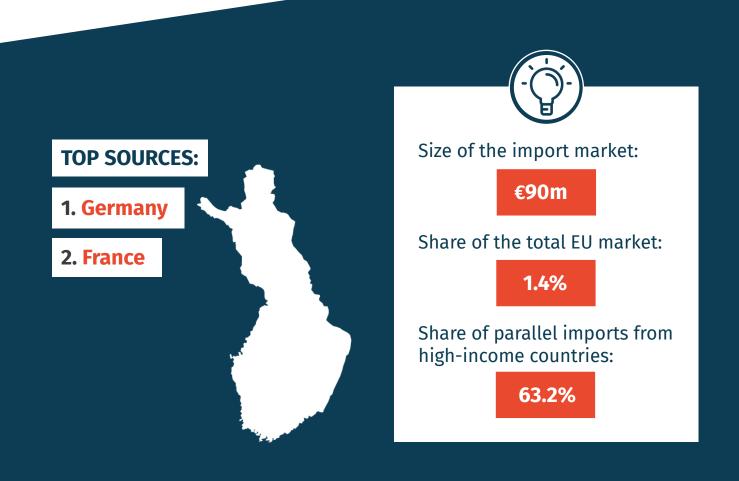
This corresponds to 1.4% of the total sales of PI in Europe, and makes Finland the 9<sup>th</sup> largest importer in Europe.

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

Finland has the 3<sup>rd</sup> largest proportion of PI medicines originating from high-income countries, with 63.2% (slightly below Sweden and the Netherlands). The two main sources for parallel imports in Finland are also countries with a high GDP per capita: Germany and France. In total those two countries account for more than 40% of the exports to the Finnish parallel import market. 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<sup>23</sup>.

In Finland, in 2021, PI accounted for a 2.7% market share in the pharmacy market and a 5.6% 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.

<sup>23</sup> Copenhagen Economics 2021: <u>https://bit.ly/3juTh17</u>.



<sup>&</sup>lt;sup>22</sup> Data from IQVIA.

ITALY

Italy is the Mediterranean country with the largest market for parallel imports, and the 8<sup>th</sup> largest at the European level. Sales amounted to €110 million in 2022<sup>24</sup>.

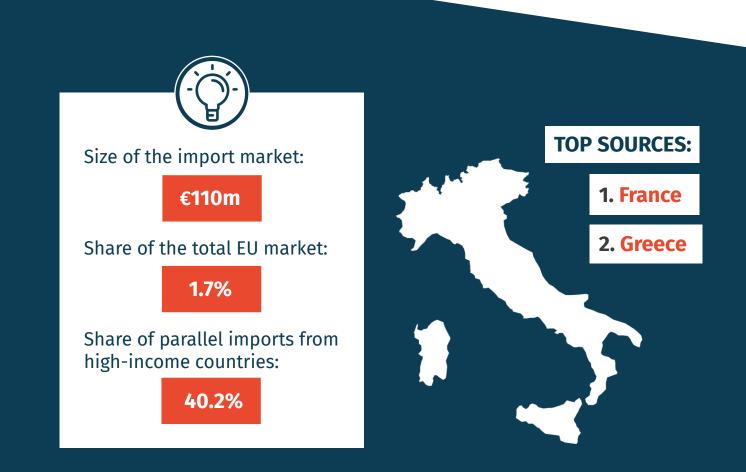
After a rapid growth in the past, the market seems to have stagnated in the last couple of years. However, early numbers from IQVIA for 2023, seem to suggest a new rapid growth coming to the Italian market.

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. In Italy, parallel importers agreed with AIFA to provide an additional 7% discount to all the medicines parallel imported to Italy. This has already brought to the Italian healthcare savings amounting to approximately 8 million Euros in 2022.

In total 40.2% of the imports still come from high-income countries, with France being the main source (14.2%) in 2022.

Italy is far below the average when it comes to exports per capita, where it is only the 20<sup>th</sup> largest exporter. However in total terms, Italy was the 4<sup>th</sup> largest exporter in as well 2022 as 2023. Italy is one of the Member States that have increased the most in light of the departure of the UK following Brexit.

<sup>24</sup> Data from IQVIA.



## POLAND

The value of the Polish market of parallel imports has been decreasing over the last years. In 2022, it amounted to  $\notin$ 90 million<sup>26</sup>, which is down from  $\notin$ 93 million in 2020 and  $\notin$ 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.

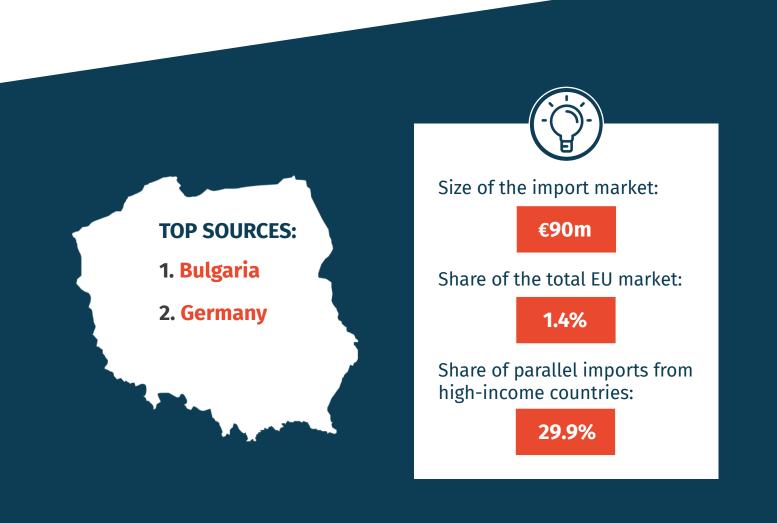
However, considering that the Polish parallel import market is among the youngest in the EU (parallel trade has only been possible since Poland joined the EU), it has developed rather quickly, and today it is an important contributor to the Polish medicines market.

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)<sup>27</sup>.

However, the Polish government has introduced unproportionate parallel export restrictions. This makes Poland one of the few countries that openly acknowledges the benefits of parallel imports while infringing EU law in relation to parallel exports.

The main source of imports in Poland is Bulgaria, followed by Germany. Around 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 2020. Poland is not among the main parallel exporters in Europe, not in absolute value nor in per capita terms.

<sup>&</sup>lt;sup>27</sup> Polish savings report 2020: <u>https://bit.ly/3cF9Ocf</u>.



<sup>&</sup>lt;sup>26</sup> Data from IQVIA.

# 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  $\in 60$  million; and in 2022 they have doubled to  $\in 120$  million<sup>28</sup> (1.9% of the total sales of PI in Europe).

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.

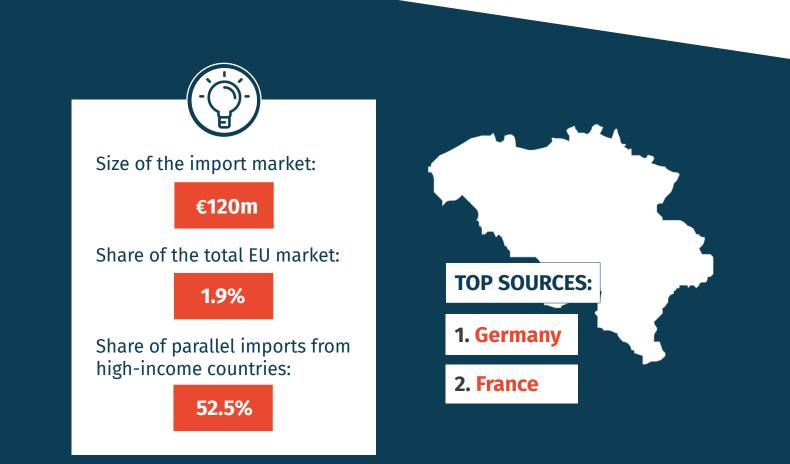
Furthermore, Belgium is the number one country in relation to the use of the so-called MEAs (managed entry agreements). These result in prices being secret, why parallel importers cannot know if they can compete or not in the market. Hence, competition from parallel imports for a number of products is *de facto* impossible.

52.5% of the parallel imported medicines sold in the Belgian market come from high-income countries. Germany and France are the top two sources in 2022.

Belgium is also above the average in exports per capita at 11<sup>th</sup> place in Europe. In total terms, Belgium was the 8<sup>th</sup> largest exporter in 2022. At the same time, Belgium is 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.

<sup>28</sup> Data from IQVIA.



NORWAY

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

Sales in Norway have been decreasing in recent years<sup>29</sup>. This makes it the smallest Nordic market for parallel imports by far.

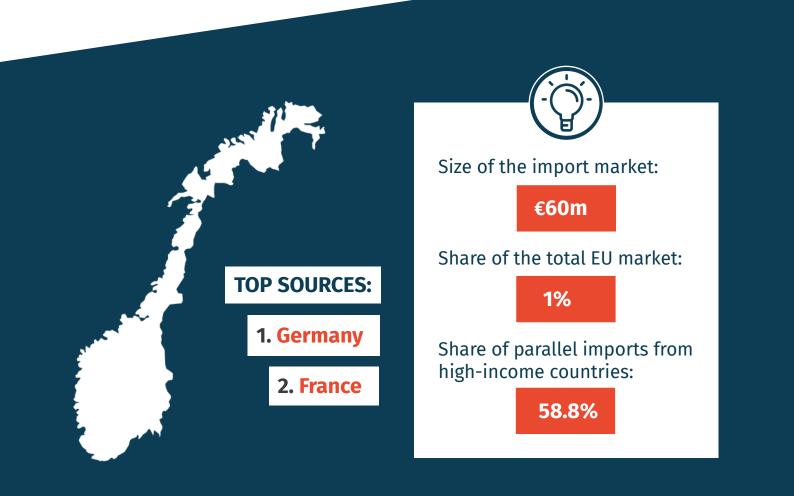
The Norwegian parallel import is not very well incentivised, which leads to sub-optimal conditions and less savings from parallel imports than in the other Nordic countries. This could easily be changed, by creating a better parallel import framework, that would ensure savings to the healthcare payers.

58.8% of the imports come from the countries with a higher level of GDP per capita. Germany is the main source by a margin, followed by France. The two together account for 38% of the Norwegian parallel imports. Norway is not one of the main sources of imports for the rest of the continent, but it ranks above the average in terms exports.

Norway is in fact the largest exporter per capita in 2023. This is a return to the 1<sup>st</sup> place Norway also held in 2018. In the meantime, Norway was 7<sup>th</sup> in 2020 and 2<sup>rd</sup> in 2022.

In total value terms, Norway is the 12<sup>th</sup> largest exporter in the EEA. This makes Norway a netexporting country as the only Nordic country. Considering, that Norway has the 3<sup>rd</sup> highest GDP per capita (and Luxembourg is not relevant at all for parallel trade), it may seem surprising that they are the largest exporter per capita.

<sup>29</sup> Data from IQVIA.



**SPAIN** 

The sales of parallel imported medicines in Spain experienced a rapid increase in recent years and amounted to  $\in 28$  million in 2022, compared to  $\in 13$  million in 2020<sup>30</sup>.

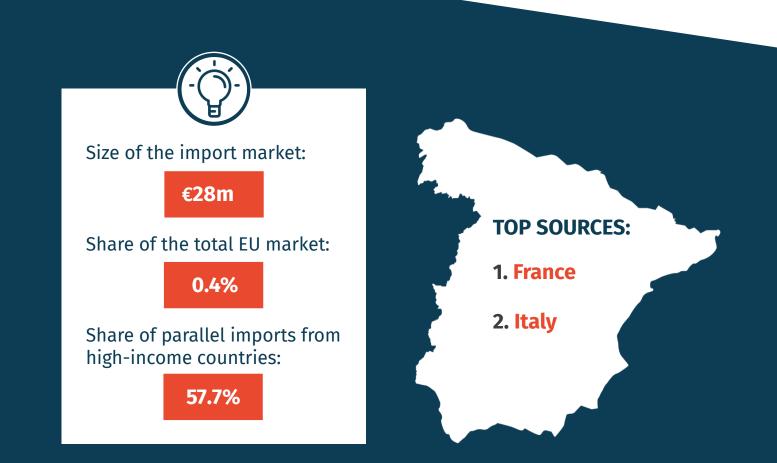
57.7% of the imports come from high-income countries. As in 2020, the top two sources of parallel import products in Spain is composed of other Mediterranean countries: France and Italy.

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 more maturity. Furthermore, it is still not possible for parallel importers to win significant contracts in hospital tendering. Hence, the hospital market is non-existent.

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 Belgium, 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 cause of shortages.

<sup>30</sup> Data from IQVIA.



FRANCE

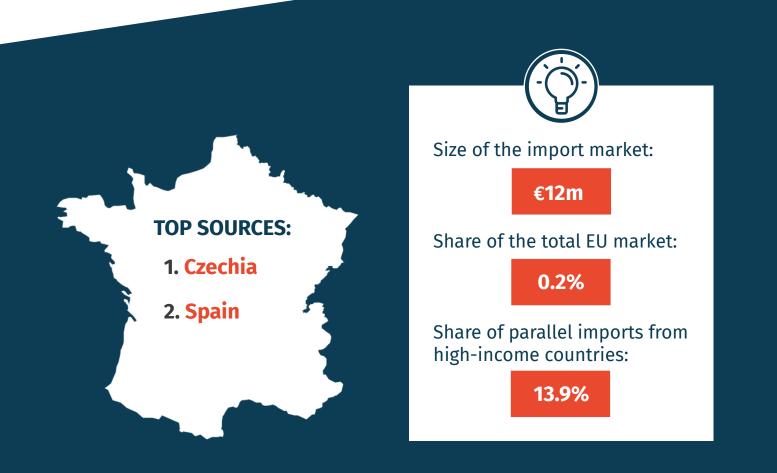
The sales of parallel imported medicines in France amounted to €12 million in 2022<sup>31</sup>, a 9% increase compared to 2020.

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, in 15<sup>th</sup> place.

It is noteworthy that, as France is the top country for Spain's parallel imports, Spain is 2<sup>nd</sup> largest source for its neighbour, with a significant part of the total share (25.0%), only preceded by Czech Republic.

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<sup>32</sup>.

France has legal provisions to ban parallel exports for individual medicines in shortage. This system is managed in a proportionate manner.



<sup>&</sup>lt;sup>31</sup> Data from IQVIA.

<sup>&</sup>lt;sup>32</sup> Cour des Comptes (2017). La Sécurité Sociale. Rapport sur l'application des lois de financement. Paris: Cours des Comptes. Retrieved from <u>https://www.ccomptes.fr/sites/</u> <u>default/files/2017-09/20170920-rapport-securite-sociale-</u> 2017\_1.pdf.

LITHUANIA

Lithuania has experienced a rapid growth of its parallel import market in the recent years, and it 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.

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

From 2021 to 2023 sales went from around €10 million to more €18 million<sup>33</sup>. Although the figure is low compared to many countries, the market share of parallel imports is already high, and is expected to grow further. We would expect a market share above 4-5% within a short time period.

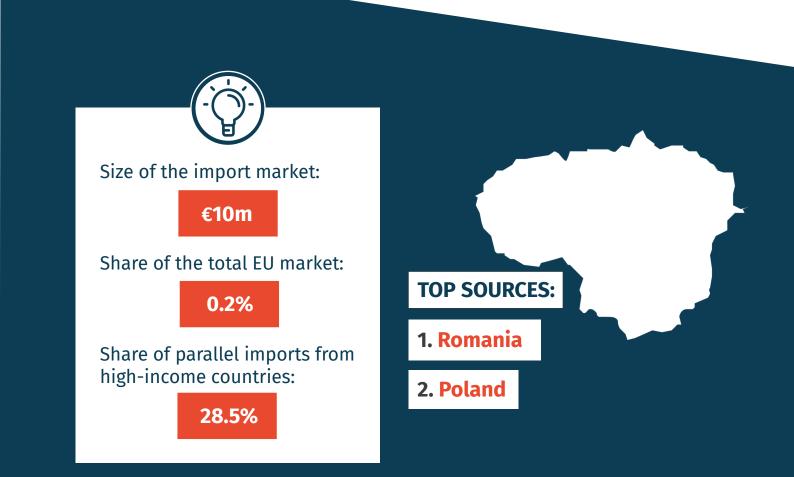
As with the other Baltic member States, Lithuania is not only reaping the benefits of traditional parallel import, but is increasingly also securing access to medicines otherwise not made available in the market by the manufacturers.

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

With 28.5% of the imports come from highincome countries, Lithuania has seen this share grow since 2020.

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

<sup>33</sup> Data from IQVIA.



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 the years before then.

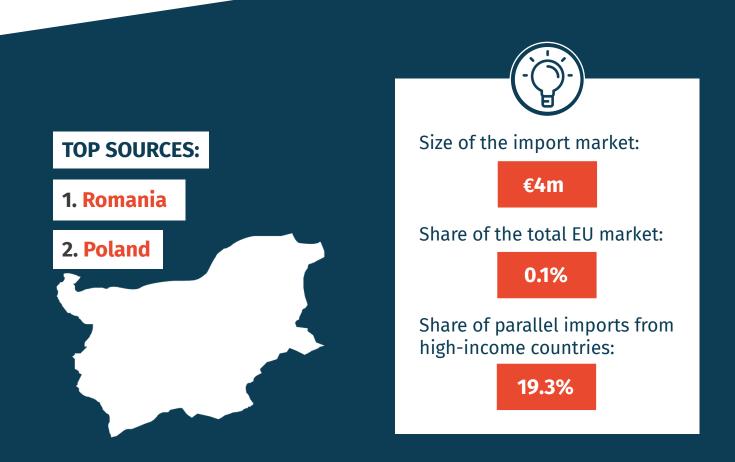
In spite of being one of the lowest priced medicines markets in Europe, parallel imports also have a great potential in this market. Especially concerning trade between Eastern European countries, which could be spurred further as companies enter the market and increase competition.

Unfortunately, Bulgaria does not allow parallel imports to receive the same reimbursement code as the originator product, which means that pharmacies are not able to dispense them to patients even with the lower prices, as there will be no reimbursement given to patients. Hence, no patients choose parallel imports for reimbursed medicines. Romania and Poland were the main sources of imports in 2022. 19.3% of all the imports came from high-income countries.

Parallel imports 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<sup>34</sup>.

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.

<sup>34</sup> Voinova, L. (2019). *560 Missing Drugs Alerts*. Bulgaria: BAMPTD. Retrieved from <u>https://parallel-trade-</u> <u>development.org/en/news/BAMPTD-news/560-Missing-</u> <u>Drugs-Alerts</u>.



# CYPRUS

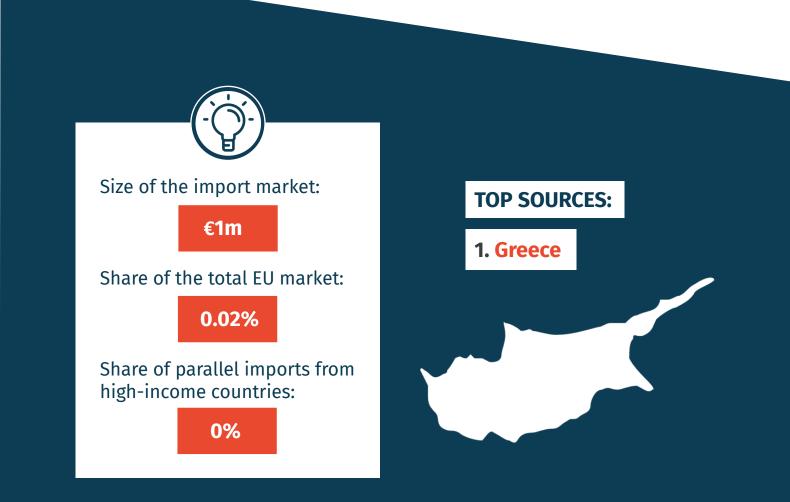
Cyprus has the smallest parallel import market of the sample, with just about €1 million in sales turnover. They are mostly sourced in its neighbour country Greece, due to the fact that repackaging needs are extremely limited, since they are already in the Greek language.

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 negligible in absolute terms, and they are also way below the European average in per capita terms. In general Cyprus has 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.



# 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.