Parallel trade: Which factors determine the flow of goods in Europe?
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INSIGHTS INTO THE MARKET SEGMENT OF PARALLEL IMPORTS AND EXPORTS AS WELL AS AN OUTLOOK ON THE DEVELOPMENT OF PARALLEL TRADE WITH PHARMACEUTICALS

Despite the ongoing harmonization in Europe, the European pharmaceutical market is divided into individual national markets. One of the consequences of this division are different price levels. Parallel traders use these price differences: They buy up originals in member states of the European Economic Area (EEA = European Union, Norway, Iceland, and Liechtenstein) with low prices and resell them in other EEA countries. Although logistics and repackaging cause considerable costs to the parallel traders, arbitrage trading with pharmaceuticals is an appealing commercial activity. The market volume of this segment of the European economy has increased noticeably in recent years.

Parallel exports and parallel imports – defining the terms

Parallel export is the exportation of pharmaceuticals which have been produced by international or multinational companies and are taken to a different national market by the manufacturer as well as export traders. The traders therefore export a parallel export.

Accordingly, parallel import is defined as the importation of drugs which have been produced by internationally operating manufacturers and which are brought into the German market by the manufacturer as well as import traders. The traders bring parallel imports into Germany.

Among physicians and pharmacists, the term parallel import is considerably more commonly used than parallel exports. This is due to the fact that historically Germany has served almost exclusively as a target market for parallel imports. However, as a consequence of the Act on the Reorganization of the Pharmaceutical Market (German: Gesetz zur Neuordnung des Arzneimittelmarktes (AMNOG)) and price comparisons on an international level, a new dynamic has developed in recent months. For many patented pharmaceuticals with “AMNOG reimbursement amounts”, Germany has already become an export country.

In this context the authors would like to point out that currently about 90% of all imported pharmaceuticals are parallel imports. There was no quantification relating to exports and parallel exports available to the authors of this white paper.
DRIVERS OF PARALLEL TRADE WITH PHARMACEUTICALS IN EUROPE

The parallel trade with drugs in the EEA is very dynamic and driven by four major factors:

1) **THE DIFFERENT PRICE OF PHARMACEUTICAL PRODUCTS IN VARIOUS COUNTRIES**

The prices of pharmaceuticals are the crucial driver of parallel trade. In the individual countries factors such as purchasing power, and increasingly also reference pricing with regard to other European countries, determine the price formation of pharmaceutical products.

A price corridor is thus established which enables parallel traders to use the divergent prices in different countries for their business.

2) **LEGAL GUIDELINES**

The legal framework also plays an important role for parallel trading within the EEA.

**Example: SHI-Modernization Act (2004) in Germany**

One of the best examples for this is the adjustment relating to the SHI-Modernization Act in Germany, which came into force in January 2004. It has led to changes in the regulation of price intervals for imported pharmaceuticals and modified minimum import quotas.

It is important to note in this context that

- the pharmacists are required to dispense imported pharmaceuticals if these are 15% or 15 euros cheaper – measured against the pharmacy retail price – than the respective original. Only parallel imports meeting these requirements contribute to fulfilling the import quota of 5%. (Note: Since January 1, 2011 manufacturer rebates need to be taken into consideration when calculating the 15/15 price gap.)

- the actual price gap between parallel import and corresponding original used to be at around 10% before 2004.

In the immediate aftermath of the SHI-Modernization Act the share of parallel imports collapsed. Many did not meet the new “15% or 15 euros requirement” the substitution rule demanded.
However, in the following years the share of parallel imports increased continually due to a growing focus on specialty drugs (including oncology products, HIV- and CNS-therapeutics) and the capping of price differences at 15 euros per package worth 100 euros or more. This price cap is a consequence of the substitution regulation which demands that parallel imports must be 15% or 15 euros cheaper.

In 1999 the share of parallel import in the German pharmacy market (purchases of retail pharmacies by value) was 2.2%. By 2010 it had risen to 12.7% (MAT December 2010). During this period, importers of pharmaceutical products firmly established themselves in the market – some of them have become highly specialized.

### Changes in health insurance regulations and other rules (2011)

Another example for the influence of legal guidelines is the raise of manufacturer rebates for drugs not regulated by reference pricing. It changed from 6% to 16% between August 1, 2010 and December 31, 2013.

The increase of manufacturer rebates brought the strong growth of parallel imports to a standstill and resulted in a stagnation of the parallel import market between 2011 and 2013.

For the first quarter of 2014 manufacturer rebates were reduced down to 6%. The fourteenth amending law to SGB V settled the manufacturer rebate at 7% – starting from April 1, 2014. Particularly due to the reduction of the manufacturer rebate, the share of oncology products and CNS-therapeutics imported into Germany has risen since then again.
Example: Regulations in other countries

Following the economic and financial crisis in Greece, the Greek National Organization for Medicines has prohibited the export of 34 medicines in February 2013. This decision was justified with a need to secure the supply of drugs within the country. Presumably the payments to pharmacies had increasingly failed and thereby encouraged export trade.

Following this decision, fewer goods could be provided by parallel traders. As a reaction they adjusted exports from other markets.

3) EXCHANGE RATE FLUCTUATIONS

The extremely volatile nature of parallel trade with pharmaceuticals within the EEA is illustrated in particular by the example of parallel imports to and parallel exports from the UK. Driven by a weak exchange rate of the British pound vs. the euro, parallel imports to the UK decreased noticeably in 2008 and particularly in 2009.

During these years, British traders “discovered” Germany as a target market for their pharmaceutical products, eventually contributing to a shortage of some medicines in the domestic market.
Supported by a strong British pound, parallel imports rose again between 2010 and 2012.

The exchange rate fluctuation generally leads to shifts in the flow of parallel traded pharmaceuticals within the European Single market. In 2012 the relative weakness of the euro in relation to the British pound resulted in a decreasing appeal of Germany as a market for parallel imports.

In 2013 the tables turned: The euro’s exchange rate turned out stronger than expected. The development of the British economy was disappointing and consequently the growth of parallel imports of pharmaceuticals into England, Wales, Scotland, and Northern Ireland stagnated. This was accompanied by a “struggling” external value of the British pound.

Since the beginning of 2014 the value of the British pound has increased considerably in relation to the euro. Following stagnating parallel imports into the United Kingdom, the coming months should see imports rise again.

**FIGURE 3: EXCHANGE RATES AND PRICING INTERVENTIONS INCREASINGLY DETERMINE THE RATE OF PARALLEL IMPORTS OF PHARMACEUTICALS**

### 4) SOCIO-CULTURAL FACTORS

The great significance of the UK – and other European countries such as Germany and the Netherlands – for European parallel trade is not only based on economic and legal parameters. In fact, these countries show a certain affinity to arbitrage activities. In consequence of this “love for trade” companies have established themselves in the European market, forming a European network – at least partially – and continuously developing parallel trade further and further.
CURRENT TRENDS IN PARALLEL TRADE WITH PHARMACEUTICALS IN EUROPE

The German parallel import market – with a share of 54% by value (total2014) – still dominates within the EEA.

As previously outlined, the importance of Germany as parallel import market is driven by price differences between the German pharmaceutical market and other national markets – with, in some instances, significantly lower purchasing power – as well as the legal guidelines in place.

Parallel imports into Germany increased after manufacturer rebates for drugs not regulated by reference pricing had been reduced from 16 percent to 6 percent (Jan-Mar 2014), respectively 7 percent (Apr 2014 onwards). Furthermore, the Oberlandesgericht (Higher Regional Court) Düsseldorf ruled that parallel imports must generally be considered in Europe-wide tenders for discount agreements. Grist to the mill of parallel importers!

The UK remains an important hub for parallel trade in Europe – as a parallel export market but also as the second biggest net-import country with a share of 15% by value. Due to the rising value of the British pound, it is likely that parallel imports into the UK will increase.

Sweden has experienced a tremendous growth in parallel trade in the past years, recently getting to hard stop driven by a new reference pricing in 2014 on mature products. Still, Sweden remains the third largest import market in the EEA with a share of 10%.

FIGURE 4: GERMANY IS THE NO.1 TARGET MARKET FOR PARALLEL IMPORTS

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Despite a relatively strong euro, several patent expiries (Lipitor among others) curbed the parallel import of pharmaceuticals into the Netherlands.

In Denmark parallel imports have recently slightly declined. Denmark is very much driven by tender business with suppliers (original manufacturers and parallel traders) competing as often as every two weeks for supplying pharmaceuticals.

Republic of Ireland: A relatively strong euro in comparison with the British pound should have led to a rise in parallel imports. Yet price reductions in the Irish healthcare system more than offset exchange rate dynamics.
Parallel imports: countries of origin

A few years ago the UK used to play a major role in supplying Germany with parallel imports. Currently, however, these imports increasingly come from South Eastern Europe.

Massive cost reductions in some healthcare systems (i.e. in Greece, Ireland, and Spain) are the driving forces behind this development. Furthermore, some Eastern European currencies (i.e. the Hungarian forint) have diminished in value compared to the euro.

**FIGURE 6:** MANY PACKAGES ORIGINATE FROM EASTERN AND SOUTH EASTERN EUROPE
Particularly oncology products and anti-psychotic drugs are selectively imported into Germany. These two therapy areas account for more than 40% of all parallel imports.

Particularly the reduction of manufacturer rebates led to rising imports of oncological products and CNS-therapeutics into Germany.

**IMPORT MARKET GERMANY AND COUNTRIES OF ORIGINS – HOW DO THE PIECES OF THE JIGSAW FIT TOGETHER?**

German subsidiaries of globally operating pharmaceutical companies lose substantial market shares and domestic sales. The origin of the pharmaceuticals is very diverse and changes over time. The IMS® Country of origin study puts the jigsaw back together.

Since March 2003 IMS Health has offered to survey and identify countries of origin for selected medications. During these years we have learned that the process of surveying and analyzing depends on the customers’ individual needs and the type of medication. Therefore it needs to be adjusted accordingly.
Objective of the IMS® survey on countries of origin: Identification of source countries of parallel traded product and quantification of the respective export volumes for a defined period. IMS uses various approaches which offer different advantages depending on the kind of drug and the favored method of distribution:

- The survey via a special panel of around 1,000 pharmacies,
- alternatively the survey via fully stocked wholesalers,
- or via individual highly specialized pharmacies

Panel of pharmacies: Using a questionnaire IMS collects information on the stock of selected community pharmacies and defined products on a specific day. For this survey IMS established a separate panel of pharmacies. The panel size of around 1,000 pharmacies guarantees a solid sample size, which ensure highly valid results. For the observation period IMS provides the following information: number of packages of the chosen parallel imports, distribution of parallel imports among the traders, graphic representation of the results, raw data of the survey (product, commercial form, central pharmaceutical number, importer, batch number, country of origin).
The IMS® country of origin study offers various benefits

The results of the country of origin study can be utilized by various business sections and in a number of different ways. Based on the identification of source countries and the subsequent quantification of export volumes, financial performance of the affiliates can be reviewed.

Furthermore, prognoses for the company’s pan-European logistics can be optimized. Indirectly, the findings of the country of origin study may also contribute to securing sufficient supplies for the national markets within Europe. Furthermore, it is possible to identify unexpected or even illegal flows of commodities and implement appropriate counter-measures.

In cases where the panel pharmacies stock only a few packages (Note: This applies to specialty drugs with very low distribution rates.), the panel does not allow us to draw valid conclusions about the countries of origins. Therefore we offer alternative surveys via wholesale or via specialized pharmacies.

**Specialized pharmacies:** Customer-tailored specialty pharmacy panels are often the first choice to maximize coverage of specialty care products with a comparably low number of distributing pharmacies: It provides information on the purchasing patterns of the major players in the market. Therefore, this highly specialized approach is superior to classical methods of qualitative market research.

**Survey via wholesale:** If the survey via pharmacies does not provide sufficient information, data can be collected as well in wholesaler storage sites. Data is collected about the stocks of parallel import goods in various wholesale storage sites. This method collects the data of defined pharmaceuticals on specific dates. Due to the expected amounts of stock, the survey via wholesale allows us to draw general conclusions about the distribution among various countries. However, the market information is not representative in the statistical sense.
Most European countries have an increasingly ageing population. This development is particularly dramatic in South Eastern Europe (Romania, Bulgaria, and Greece) and in the Baltic countries. When looking at the larger European countries, particular attention is drawn to the demographic change in Germany and Italy. According to a UN survey by 2045/50 only Luxemburg and the Republic of Ireland will see the number new born babies exceeding the number of deaths.

European healthcare systems tend to be publicly funded. In Germany, France, the UK, Italy, and Spain 60 to 70+% of the respective healthcare system is publically funded. Although for some years the Statutory Health Insurance in Germany was able to create a surplus – due to high employment rates – the European healthcare systems will eventually need to reduce costs. In some countries in the south of Europe, such as Greece and Spain, the economic crises will bring about these cuts sooner. In other countries ageing populations will lead to cost reductions medium to long term. The pressure on the prices of pharmaceuticals will increase!
The Act on the Reorganization of the Pharmaceutical Market raises the question whether a combination of early benefit assessment, reimbursement amounts, and price referencing of pharmaceuticals throughout Europe will trigger prices downward spiral. The manufacturer’s prices in 15 EU-countries (F, GB, I, E, S, A, NL, B, IRL, DNK, FIN, GR, P, CZ, and SK) will be one criterion for the reimbursement amounts.

The lion share of these countries has a lower GDP per capita than Germany. Only Austria, the Netherlands, and Sweden exceed Germany in economic power – and consequently probably also in purchasing power.

Yet, prices for pharmaceuticals in Germany are compared with prices in countries that are in a very different situation. In many of these countries the economic performance is significantly lower, their social security systems run high deficits and the purchasing power of their population is generally less than in Germany. Reciprocal price referencing among these countries leads to falling prices – which further increases the pressure.

One question remains unanswered: Will this downward spiral lead to a convergence of prices for pharmaceuticals in Europe? On the one hand “lower prices“ will be “imported“ into Germany from economically weaker countries, price levels could equalize, and parallel import into Germany would decrease. On the other hand prices might change permanently. A price reduction in one European country would make imports to other countries more appealing.
Many experts are critical of international price referencing, in particular because of the discrepancy between the economic situations in the individual EU countries. Here are some opinions:

„Conclusion from the evidence: Launch delay and non-launch are more likely in countries with lower prices. Referencing from high-price to lower-price EU countries contributes to launch lag in the lower-price countries. Referencing from high-price EU countries also contributes to higher prices, relative to their income, in lower-price EU countries. Referencing and parallel importation by high-income countries create a dilemma for lower-income countries: Pay high prices, relative to their income, or forego availability."


„External reference pricing will soon reach the end of its useful life cycle (when almost all countries reference each other and prices converge, the differences between countries diminish)"


„This study comes to the conclusion that EPR is a dynamic and widely used pricing policy in Europe, with many different national characteristics; (…) However, we still see room for improving by implementing more detailed legislations (…)”

PARALLEL EXPORTS FROM GERMANY – A NEW DYNAMIC

Since the end of last year more and more patients, pharmacists, and physicians have been reporting shortness of supplies for certain drugs – following the decision on the final reimbursement price after the AMNOG assessment.

In June 2014 the German Association of Research-Based Pharmaceutical Companies (VFA, Verband Forschender Arzneimittelhersteller e.V.) analyzed 45 products with a reimbursement amount. The study showed that 80% of the German prices were already below the European average; almost half of them even below the smallest reference prices.

![Chart showing parallel imports and reimbursement levels.](image)

**FIGURE 12: SINCE AMNOG*: REIMBURSEMENT LEVEL BELOW EUROPEAN AVERAGE**

Parallel trade within the EEA is driven by differences in the legal framework, fluctuating exchange rates, and price differences in the individual national markets. If a relatively high price level encourages parallel imports, by implication the opposite – low price levels – can be a decisive factor for low parallel imports and declining shares of parallel imports, respectively.

A recent analysis shows that the share (in value) of parallel imports “under reimbursement amount” (= low relative price level) is actually significantly smaller than the share of parallel imports without reimbursement. Furthermore, the share (in terms of value) of parallel imports with reimbursement amounts is declining, while the share of parallel imports without reimbursement is continuously rising.
Apparently medications with reimbursement amounts are subject to “different laws of parallel trade” than other pharmaceuticals which are not governed by the AMNOG. This insight also explains why Germany evolves into a parallel export country – at least for medicines with reimbursement amounts.

Case study parallel export: Gilenya

An example of parallel export from Germany is the product Gilenya by Novartis.

Background: After agreeing on a reimbursement amount, the product has been released for wholesale at a price of 1,300.32 euros (Gilenya 0.5 mg 28) since February 2013. The introductory price was 1,850.00 euros. Consequently Novartis reimburses a rebate of 549.68 euros (rebate according to §130b SGB V).
Example: delivery problems with Gilenya. Reports on Facebook:

“Do you also have delivery problems with Gilenya?”

“I still haven’t got any Gilenya. Today they finally ordered it directly from Novartis. (…)”

“I tried to get it from my pharmacy on Friday. They said it was not available at the moment but would get back to me as soon as they had some. This has never happened before. Luckily, I still have enough for about a week.”

Source: FACEBOOK, German language group, December 17, 2013

In all 15 EU countries with reference pricing (F, GB, I, S, A, NL, B, IRL, DNK, FIN, GR, P, CZ, and SK) the manufacturer’s price is higher than in Germany – even in Bulgaria (1,548.62 euros) and Romania (1,610.00 euros), two of the countries with the weakest economies in Europe (current as of February 2013).

A consequence of the low reimbursement amount: Parallel traders buy goods intended for the German market from pharmacies and pass them on to other European countries. Target markets of these parallel exports are particularly Denmark (manufacturer’s price: 1,753.63 euros), Sweden (1,734.74 euros), and Austria (1,682.20 euros).

![FIGURE 14: PHARMACIES BUY MORE GOODS THAN THEY DISPENSE](image-url)
Comparing the amount of Gilenya community pharmacies buy to the amount they dispense is another piece of evidence supporting the assumption that Germany is developing into a parallel export market for pharmaceuticals with reimbursement amounts. At a peak, up to 12% of the packages intended for the German market were exported to other European countries. Obviously, these medicines are not available to patients in Germany.

**QUO VADIS EXCHANGE RATE? QUO VADIS PARALLEL TRADE?**

It is difficult – if not impossible – to assess in which way exchange rates will develop, since the value of a currency depends on a large number of different factors.

Currently the British economy is booming. The economy is expected to grow by 3% or more. This positive development also means the British pound is increasing in value. Drivers of the boost are the central banks expansionary monetary policies, a significant rise in household spending, and the recovery of the real estate market “around London”. However, due to the deficit (Note: Imports are a lot higher in the UK than exports.) and high debts among the citizens, many economists assume that this trend is not sustainable and that the British pound is overvalued. Although the public deficit decreased slightly, at 6.8% of GDP (in 2013) it is still very high. Some experts even expect a “sterling crash”.

One cause for a possible “crash of the pound” might be the referendum on Scottish independence. Furthermore, the referendum on leaving the EU endangers the exchange rate of the currency. Additionally, a new parliament will be elected in 2015. A shift in direction – e.g. away from the economy-friendly policies of the Conservative government – entails further risks for the currency market.

The weak Swedish economy is also recovering after a disappointing GDP in 2013 (just 1.5% growth). For 2014, however, the GDP is expected to grow a significant 2.6%. Might this lead to an increased value of the Swedish krona in the coming months?

Private household consumption and increased investments in highly innovative Sweden might see the Swedish currency soaring high again. In the face of low interest rates and rising real estate prices, however, such a development entails substantial risks – according to the “Neue Zürcher Zeitung” (a Swiss national newspaper). The months to come will be exciting.
It is a fact that a heterogeneous economic development (i.e. in principle positive economic developments in Germany and the UK – no or little economic recovery in Southern Europe and other European countries) will increase the gap of purchasing power among the European countries.

A major driving force for parallel imports and exports – price differences, or rather exchange rate fluctuations, in the national markets – will remain and might grow even stronger.

FIGURE 15: 4 FACTORS WILL CONTINUE TO DETERMINE THE FLOW OF GOODS IN EUROPE
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References

Dr. Alexander Frenzel / Armin Maier / Frank Weißenfeldt – „Parallelimporte von Arzneimitteln in Deutschland“, Pharm. Ind. 73, Nr. 1, 44-48 (2011)

Dr. Alexander Frenzel / Armin Maier / Frank Weißenfeldt – „Parallelimporte: ein Ausblick“, Pharma Relations 03/2011


Dr. Stefan Lieck – „Der Parallelhandel mit Arzneimitteln“, GEW Band 10, Hrsg. Dr. Anja Steinbeck und Dr. Christoph Ann LL.M., Carl Heymanns Verlag, Köln/München, 2008

Frank Weißenfeldt – „Arzneimittel-Parallelhandel in Europa“, Pharm. Ind. 76, Nr. 2, 180-185 (2014)

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With more than 100 subsidiaries worldwide, IMS combines relevant healthcare information with great analytical knowhow and extensive experience in consulting. Our services help customers in the field of Life Science as well as healthcare providers, payers and political decision makers to improve the health of patients and to further their economic success.

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