



## ***Full Report***

# **Secondary analysis of indirect savings effects and potentials of parallel imports of pharmaceuticals**

**inno AG**

for the

European Association of Euro-Pharmaceutical Companies (EAEPC)

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## 1. Assumptions and definitions

The analysis of the competitive effects of re- and parallel imports on the German pharmaceuticals market is based on a data set of historical price data from the Informationsstelle für Arzneimittelspezialitäten (IFA) and statistics on turnover, sales and market shares from the market research institute INSIGHT Health GmbH & Co. KG, which kohlpharma GmbH, a member of EAEPC, provided to inno AG.

The **market share of reimports and parallel imports** of prescription drugs on the German pharmaceutical market based on the selling price of the pharmaceutical company amounted to 8.9% for all importers between 2011 and 2017. This market share is primarily determined by the mandatory import quota for pharmacies (up to at least 5% of turnover per health insurance fund), which, if the sale of an exactly equivalent or approximately equivalent import preparation is not excluded by prescription, must sell such a preparation if it is 15% or 15 € cheaper than the original preparation. Overall, the total market share of parallel imports of all preparations contained in our dataset is quite stable and fluctuates between 13% and 14%.

**Direct savings** can easily be calculated, they result from the price difference between the original preparation and the imported preparation. However, since it is assumed that competitive pressure also has an impact on the pricing policy of the originator companies, we assume that the actual savings consist not only of how much cheaper parallel imported drugs are, but also of additional indirect savings:

**Indirect savings** result from price concessions by original equipment manufacturers, i.e. price reductions implemented by original equipment manufacturers in response to potential or actual competition from parallel importers. These savings can be calculated as the amount by which manufacturers lower prices in a competitive parallel trade situation multiplied by the volume of medicines sold on the market during the analysis period.

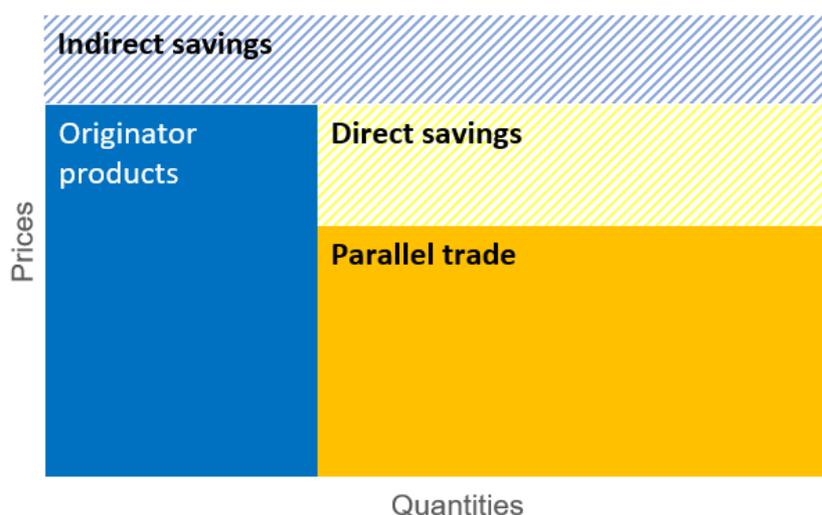


Figure 1: Shares of savings

**These calculations are based on a purely hypothetical situation:** how would the original price have developed if there had been no potential or actual competition? However, this price cannot be determined directly and is based on assumptions resulting from the price

development of comparable medicines without competitive pressure and the assumption of a causal link between parallel imports and price changes of the original product.

It should be noted that the following comments refer only to **indirect savings in the German market**. The following products and savings are not taken into account:

- Products that compete with generics because indirect savings in this product group are hardly calculable: Discount agreements cannot be viewed, so that the actual net selling price of the reference drug cannot be determined. Such discount agreements between the original manufacturers and the health insurance funds can also undermine the mandatory sale of imported drugs. **Thus it can occur that import alternatives to original preparations for patients of some health insurance companies no longer fall under the 15/15 rule and therefore do not have to be delivered**, whereas the same drug for patients of such health insurance companies without a discount contract for it falls under the 15/15 rule and has to be delivered. Therefore the influence of the discount contracts is sometimes negative, if savings for all patients and health insurance companies are to be obtained, because by the delivery of an import medicament the savings could be larger, than the exclusive saving by price reductions of the original products with discount contracts.
- **Direct savings** resulting from the price difference between the original product and the imported product and their market shares.

Accordingly, 4,297 different products emerge from Kohlpharma's data set of 27,779 drugs. **One product comprises all substitutable drugs**. For the reasons given above, products for which generics are on the market are deducted. This includes generics for which a discount agreement exists for the original drug product and also products for which a biosimilar is on the market. After this exclusion, 2,159 products remain. Finally, we will only consider those products for which Kohlpharma itself has brought an imported drug onto the market. These are 1,229 products that have been analysed.

Other factors influencing the original price, which are not directly taken into account and systematically underestimate the level of indirect savings, are also factors that reduce prices:

- the market pressure caused by parallel imports, which is reflected by the fact that the prices of the original products increase less rapidly, a double-indirect effect
- the effect of potential competition from parallel imports, since it is purely counterfactual and difficult to calculate. This effect could lead to price reductions and discount negotiations between the original manufacturers in order to prevent the market entry or significance of the parallel import for the corresponding drug. This can also be observed with products whose patent protection is about to expire. Original prices are lowered in order to make the market unattractive for competitors.
- Disclosed discount agreements for certain drugs for sale to patients of certain health insurance funds, for which the net sales prices are lower than without a discount agreement. These are an implicit response to import quotas and competition from imports.

## 2. Indirect saving potentials through parallel imports

If parallel trade exerts competitive pressure on the original equipment manufacturers, we assume that increasing market shares for imports will ceteris paribus lead to a reduction in the prices of original products. Prices were also lowered at the time of market launch in order to limit competition from imports as far as possible. For example, the prices of original products with competition from parallel imports are lower than those without such imports, which means indirect savings. This is linked to the influence of parallel imports (actual or potential) on the price of the original product, which is presented as indirect savings.

In order to estimate the indirect savings, the **correlation between the original price and the market share of parallel imports is considered over time** ( $p_o \times V_I$ ). Positive correlations are increases or decreases of both values ( $\uparrow \times \uparrow$  or  $\downarrow \times \downarrow$ ), negative correlations are opposite ( $\uparrow \times \downarrow$  oder  $\downarrow \times \uparrow$ ).  $\uparrow$  includes "no change". The increase or decrease of the values is determined over the analysis period from 2011 to 2017.

**Negative correlations are assessed as market pressure.** The number of products for which a negative correlation was found in the data set under consideration is 573. This corresponds to 46.62% of all 1,229 products examined.

Examples of products with negative correlation are Edurant and Giotrif. There is no generic drug available for each of the named drugs. The following diagrams show the development over time for both drugs:

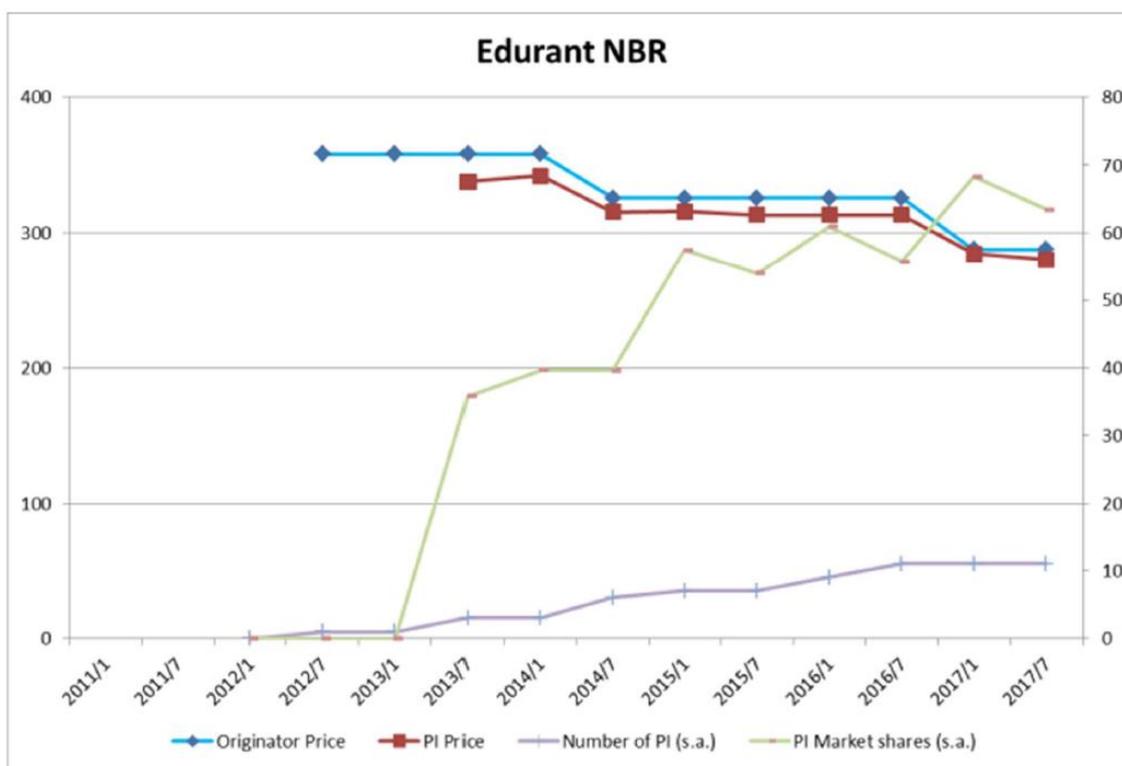


Figure 2: Market development Edurant

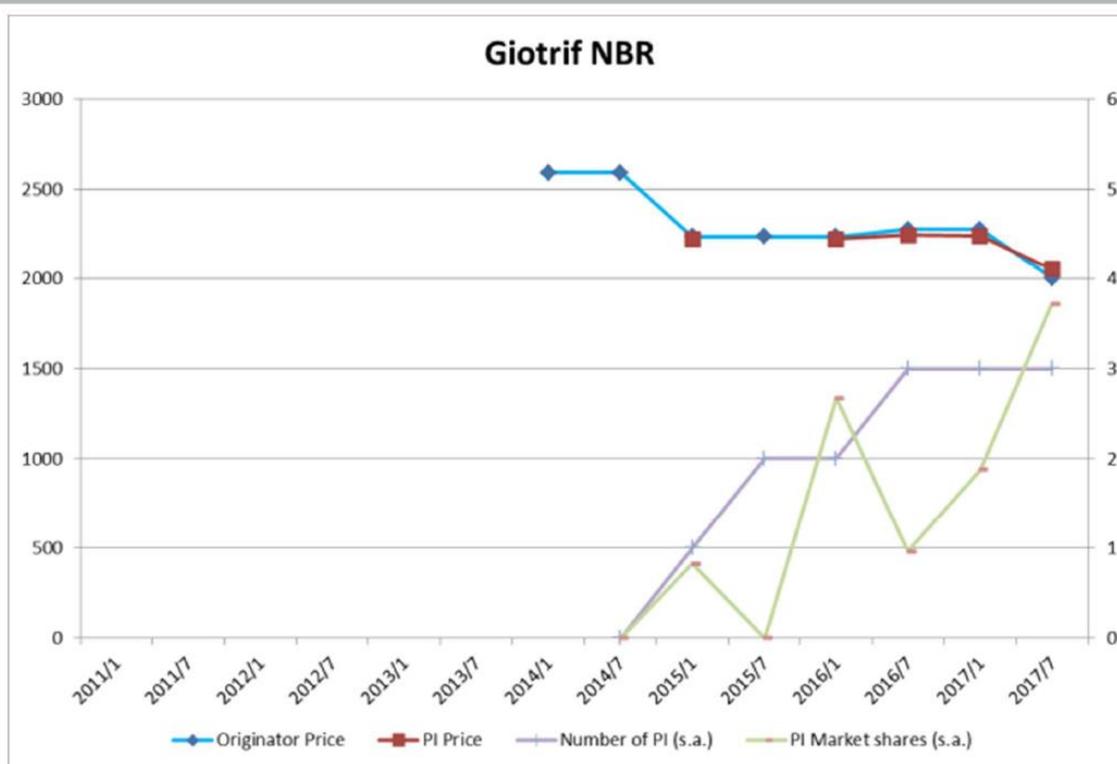


Figure 3: Market development Giotrif

It can be seen from the graphs that, as soon as the market share of parallel importers is >0% and increasing shares are recorded, it can be seen in the following observation periods that the prices of the original products fall. The blue graph for the price development of the original products over the analysis period and the green graph for the development of the percentage market share of the parallel importers run, with smaller fluctuations, in opposite directions. This corresponds to the negative correlation described above.

For the product "Edurant" the market share of the parallel importers increases from 2013, the corresponding market pressure can be observed in the price development of the original products, namely a decrease of the price.

It is similar with "Giotrif", the market entry of parallel importers in 2014 leads directly to a price reduction of the original product, with a further increasing market share of parallel importers from 2016, the price for the original product decreases again. A further price reduction combined with an increase in the market share of parallel importers can also be observed for "Edurant" between 2016 and 2017.

The correlation coefficients for "Edurant" are -0.76 and -0.78 for "Giotrif".

One reason why negative correlation cannot be observed for all products with import market share is also the import quota itself: Pharmacies are currently obliged to meet an import quota of 5 percent per health insurance company and quarter. In order for an imported medicine to count towards the import quota of the respective pharmacy, it must fulfil the so-called 15/15 rule. This means that the imported drug must be at least 15 percent or 15 euros cheaper than the original. Insofar as the original manufacturer only lowers his prices so much that the corresponding product is neither 15 percent nor 15 € cheaper than the import alternative, pharmacies are not obliged to sell the cheaper product. Strictly speaking, there is no incentive for pharmacies to sell the cheaper imported products, as imported medicines which do not comply with the 15/15 rule cannot be counted towards the import quota of pharmacies. For

them it is irrelevant whether they supply an original product or an imported product as long as the corresponding import quota is met. This is significantly lower than the proportion of pharmaceuticals that can be imported by a pharmacy: the proportion of pharmaceuticals that can be imported is 25% or more, the import quota is only 5%. Since the market volume of original pharmaceuticals is many times higher than that of imported pharmaceuticals, it is more likely that more expensive original pharmaceuticals will be sold because they no longer fall under the import quota. As a result, fewer parallel imported products are sold and the market share of parallel imported products decreases. Accordingly, a positive correlation can be found because market pressure leads to a price reduction of the original, but at the same time the import quota is undermined, which thus has a negative influence on the market share of the imported product.

Another reason why negative correlations do not occur with all products with import market share is the ERP system (External Reference Pricing System). The reason is that the original manufacturer does not want to lower the price in Germany for products for which this is the case, since price formation in other EU countries also refers to the price level in Germany and higher prices have a positive effect there for the original manufacturer. This also happens at the expense of the market share of the original product on the German market; **such products are removed from negative correlation and thus from market and price pressure, which are the calculation basis for indirect savings in our study.**

The indirect savings are initially estimated only for products with a negative correlation of  $p_o$  and  $V_I$  by calculating the difference between a hypothetical price and the observed prices and multiplying it by the sum of the quantities sold by the original manufacturers and parallel traders. This hypothetical price is the price that would have prevailed without parallel imports entering the German market and is therefore conservatively set at the average original price before parallel importers enter the market. This includes the assumption that the market price would not have changed without competitive pressure.

The price difference is calculated with  $\Delta p = p_o - p_H$ , where  $p_o$  is the current original price and  $p_H$  is the hypothetical price, i.e. the original price before parallel importers enter the market. The price difference is calculated for each product (each product class of substitutable medicines). Subsequently, **for each product**  $\Delta p$ , the sum of the number of product units distributed by original manufacturers and parallel importers (hereinafter referred to as volume) is multiplied, resulting in the indirect savings  $E_j$  for a product  $j$ . The price difference is calculated for each product class of substitutable medicines:

$$V_o + V_I = V$$

$$\Delta p_j * V_j = E_j$$

In order to calculate the average total savings per year in the named product group, the individual savings per product and volume are added up and divided by the number of years concerned (2011 to 2017), i.e. 7.

$$E = \frac{\sum_j E_j}{7} = \frac{\sum_j \Delta p_j * V_j}{7}$$

$j$  denotes the counting index that runs through all the products concerned, in particular their price differences and volumes. However, since it is only possible to calculate this saving for a fraction of the 573 negatively correlated products, this approach focuses on those products for which parallel importers enter the market between 2014 and 2017, even in order to be able to calculate an average price of the original manufacturer before market entry more precisely. The price difference could be calculated in detail for 73 products. Assuming that all original prices for negatively correlated products must have been influenced by parallel imports when they first came on the market, we extrapolate to the entire sample of products with negative correlations using the proportion of products used in the analysis measured by their market value.

The calculated saving then amounts to 61,935,554 €, which corresponds to 16.7% of the turnover of the original manufacturers ( $U'_o$ ) among the negatively correlated products.

### 3. Extrapolation to the entire import-relevant market

If we now refer the above results to the entire import-relevant market, we compare the current situation with the best possible situation in which the negative correlation affects all products there and assume that the average savings will also be borne there. The reason for this is the above-mentioned assumption that there are drugs for which there are influencing factors on the price reduction that superimpose a specific quantifiable price-reducing effect of parallel imports. These include the double-indirect effect described above and the effect of potential competition from the parallel import, which results in a lower price when the original product is introduced to the market in order to prevent parallel imports from entering the market. The products used in the analysis represent only a fraction of the import-relevant market.

In order to consider the import relevant market, the following calculations are made: <sup>1</sup>: The total market (turnover) of prescription drugs is considered, which amounted to more than 48 billion € in 2018. The turnover of those drugs which are subject to generic competition, drugs without import alternatives and drugs for which there are discount agreements for the original product are deducted. The latter are only 50% deducted, as parallel imports lead to indirect savings if the original manufacturers are persuaded to negotiate such discount agreements. Since the scope of the effect is hardly calculable, we use the indifference principle to refer to half of local sales. The indirect savings calculated by us are only achieved in the import-relevant market.

<b>Total market (turnover) of prescription-only preparations</b>		<b>48.263.183.731 EUR</b>
less	Prescription-only preparations with generic competition	21.827.199.621 EUR
less	Prescription-only preparations without import alternative	8.416.484.866 EUR

<sup>1</sup> Framework agreement on the supply of medicinal products in accordance with § 129 Paragraph 2 SGB V in the version of 1 January 2019.  
Available at: [https://www.gkv-Spitzenverband.de/media/dokumente/krankenversicherung\\_1/arzneimittel/rahmen-vertraege/apotheken/20190101\\_Arzneimittel\\_Rahmenvertrag\\_129\\_Absatz-2\\_SGB-V.pdf](https://www.gkv-Spitzenverband.de/media/dokumente/krankenversicherung_1/arzneimittel/rahmen-vertraege/apotheken/20190101_Arzneimittel_Rahmenvertrag_129_Absatz-2_SGB-V.pdf). (Accessed: 1st April 2019)

<i>Prescription-only preparations with original discount agreement</i>		10.088.449.134 EUR
less	<i>50% of prescription-only preparations with original discount agreement</i>	5.044.224.567 EUR
<b>import relevant market <math>U_1</math></b>		<b>12.975.274.677 EUR</b>

In order to relate the above calculated savings of 16.7% of original manufacturer sales among the negatively correlated products to the entire import-relevant market, we assume that import sales are also subject to competition that leads to similar savings effects. In addition, the savings of 16.7 % are related to the total import-relevant turnover of EUR 12.975 billion and not only to the percentage share of pharmaceuticals which exhibit a negative correlation between the original price and the import price (see above, 46.62 %). The following formula is used to calculate the indirect saving of 16.7 % of the import relevant market (turnover):

$$\frac{\text{turnover}}{\text{savings}} = \frac{100\% - 16,7\%}{16,7\%}$$

$$\text{savings} = \text{turnover} * \frac{16,7\%}{83,3\%}$$

$$\text{savings} = 12.975.274.677 \text{ EUR} * \frac{16,7}{83,3} = 2.601.285.559 \text{ EUR}$$

This calculation is based on the following assumptions: The savings of 16.7 % are not related to the turnover of the original importers, but represent the savings made in relation to turnover in the import-relevant market. Thus, this turnover of the original importers corresponds to 83.3 % of the turnover that would have been made if there had been no parallel imported medicines on the market. Together with the savings, this results in the full 100 %, the turnover which the original importers would have achieved without market pressure from the parallel importers.

In relation to the total import-relevant market, this results in **indirect savings of around EUR 2.6 billion.**

According to a recent study by Prognos AG<sup>2</sup>, the direct savings in 2017 will amount to EUR 264 million. These savings are lower than the indirect savings, and it can therefore be seen that the total savings achieved by parallel imports are significantly underestimated only on the basis of the direct savings. These are significantly lower than the indirect savings and do not explain why the original manufacturers vehemently oppose drug imports. Only the indirect savings make it clear why original manufacturers are opposed to a mandatory import

<sup>2</sup> Philipp Kreuzer, Heidrun Weinelt & Johann Weiß. Finanzielle Auswirkungen des Imports von Arzneimitteln auf das Gesundheitswesen. Prognos AG Available at: <https://www.prognos.com/publikationen/alle-publikationen/873/show/00f1bebd0dbe0264d024b3def8e1e605/>. (Accessed: 1st April 2019)

quota and in favour of higher legally binding price differences between original and imported drugs. The latter in particular would make the arbitrage business conducted by pharmaceutical importers unattractive and thus reduce competition from reimports and parallel imports.