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Indirect Savings from Parallel Trade in the Pharmaceutical Sector: the German and the Swedish cases

European Association of Euro-Pharmaceutical Companies

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Introduction

1. The legal movement of a pharmaceutical (or any) product from one Member State to be commercialised in another, after such product has already been legally put in the market by the manufacturer, is known as parallel trade of medicines. This is carried out by third independent parties (parallel traders or parallel importers) who compete with the original manufacturer in the importing/destination country to sell the product.

2. Parallel trade of medicines exists because parallel traders take advantage of price differentials to resell the products purchased in one country where an individual drug is less expensive into another where the same drug is more expensive. These price differences can result from country-specific market regulations or from the commercial strategies followed by the manufacturers.

3. Parallel importers are not the main beneficiaries from parallel trade. To the extent that there is competition between parallel traders and originators, or among different parallel traders, the main beneficiaries are the consumers, who pay less than they would if such competition did not exist. Beneficiaries range from national governments through social health systems and insurance companies, to hospital, pharmacies, and -ultimately- patients.

4. The benefits from parallel trade are mainly achieved in two ways:

   a)   Through the supply of less expensive medicines. These are referred to as **"direct savings"**; and

   b)   Through the creation of intra-brand competition between the original manufacturers and the parallel traders, which results in price reductions that the manufacturers concede as a response to actual or potential competition from parallel traders. These are referred to as **"indirect savings"**.

5. The potential for savings through parallel trade is significant, especially for patented products that do not face competition from other sources such as generics. Hence, much attention has been devoted to this subject over the last two decades, and many authorities apply regulations to encourage parallel trade. So far, however, the different analyses to quantify the extent of savings from parallel trade have produced different results. It is also important to note, though, that the savings identified might only represent a fraction of the potential savings, as manufacturers often impose restrictions to prevent or hinder parallel trade.

6. This study further contributes to the empirical assessment of the savings generated by parallel trade, particularly in relation to indirect savings, which have received less attention in the economic literature. Moreover, we follow a more ambitious approach considering not only a small sample of products or quantifications based on anecdotal evidence -as have done other analyses- but rather a quantitative analysis based on thousands of products for the German and Swedish markets.

Germany

7. Free pricing of new medical products in Germany is currently limited to a short period of time after market launch. Thereafter, prices are based on the outcome of an "early benefit assessment", and there is also a number of statutory cost-cutting instruments in force, such as mandatory rebates, and quotas for generics and parallel imports.

8. An analysis of the competitive effect of parallel imports on the German market for pharmaceutical products has been conducted based on data provided by parallel import companies. Essentially, the dataset contains information on volumes and revenues of medicines that were sold by originators as well as parallel importers in Germany in the period from 2011 to 2017. Overall, approximately 1,300 products have been analysed.

9. We have undertaken a correlation analysis to examine whether increasing parallel trade market shares, for products subject to parallel trade competition, correspond with decreasing originators' prices. Such a correspondence would clearly reveal a pro-competitive effect from parallel trade. A positive correlation, however, does not mean the absence of competitive effects from parallel trade, since this could also be associated with a reduction in the rate at which originators' prices increase for some products.

10. Our analysis shows that correlation coefficients tend to be evenly distributed: there are products for which changes in originators' prices are very much aligned with the strength of market presence by parallel importers (correlation coefficients close to -1); however, there are other products for which the correlation coefficients are positive. This, however, as we have stated, does not mean that competitive pressures are restricted to a subset of products since:

    a) Parallel trade always exerts competitive pressure, but this is often reflected through a reduction of the rate at which the originators' prices increase;

    b) Manufacturers could prefer not to lower prices since Germany is often used as a reference under the External Reference Price system in other countries. Thus, manufacturers would rather lose market shares to parallel importers in Germany but maintain their price levels in order to keep prices up in other national markets; and/or

    c) Products apparently not affected by parallel trade can indeed be reducing their prices but only within a rebate scheme. Although we had some information as to which products are subject to rebates, the specific terms and conditions of these agreements are confidential and therefore no quantitative analysis could be conducted.

11. Indirect savings were estimated for products showing negative correlations by computing the difference between the "counterfactual" price and the actual observed prices, and multiplying that difference by the sum of volumes sold by originators and parallel traders. The counterfactual price is the price that would have prevailed if parallel imports had not entered the German market. For estimating this price, we have relied on one main approach: the average price prior to entry of parallel imports for those products that experienced entry within the period analysed. We have then extrapolated the results to the full dataset.

Sweden

12. In order to receive market authorization for the commercialization of a pharmaceutical product, pharmaceutical companies must send an application to the authority, who analyse the medicine's quality, safety and efficacy. The drug is then classified as either prescription-only or over-the-counter.

13. The application must also include a proposed price for the medicine, although its inclusion into a reimbursement list and its final price is ultimately decided by the authority -based on the benefits brought about by the product- for medicines included in the benefits scheme.

14. For the Swedish market, the analysis was performed on a dataset also provided by parallel import companies. The frequency of the observations is monthly and covers a rather short period of time, from July 2015 to June 2018, for about 16,000 different medicines, 4,050 of which faced parallel import competition.

15. The data was processed in a similar fashion as in the German analysis, so that market shares of parallel traders were contrasted against originators' prices for those products not facing generics competition (about 1,080).

16. The results are similar to those for Germany: correlation coefficients tend to be evenly distributed; there are products for which changes in originators' prices are very much aligned with the strength of market presence by parallel importers (correlation coefficients close to -1); however, there are other products for which the correlation coefficients are positive.

17. Indirect savings were estimated in a similar way as in the case of Germany.

Results

18. Indirect savings in Germany were found to represent **16.7%** of the originators' revenues for those products with negative correlations that faced parallel trade entry within the analysis period. This can give a better idea of the dimension of the savings in relation to the market. The results for Sweden are similar, with parallel trade representing **12.3%** of the market supplied by originators.

19. Under the assumption that parallel trade must have affected all the products in a similar way when this first entered the market, these results can be extrapolated for the entire market.

20. The saving quantified can be reasonably interpreted as only a lower bound of overall indirect savings. This is because the methodology pursued is very conservative since it only considers savings that can be inferred from a visible relationship between parallel trade and product prices, leaving out indirect savings due to the threat of market entry from parallel traders (potential competition), and savings by means of rebates or discounts whose information is not publicly available.

21. Moreover, these results only reflect a portion of the savings that could be accrued if manufacturers did not engage in various practices that hinder or prevent parallel trade. Besides, the extent of the savings could be also limited by the ERP systems that encourage pharmaceutical companies to keep prices up in countries such as Germany and Sweden, despite facing competition from parallel traders.

1.   Introduction

Parallel trade arises from the limits of patent protection, whereby the rights holders cannot usually restrict second-party sales of their products. In other words, for patented products, monopoly rights are exhausted after the first sale. This can give rise, under certain circumstances, to an important commerce of patented products when there are significant price differences across consumers or regions that can make such trade profitable. The pharmaceutical industry offers an especially relevant case for this type of trade.

Technically, the legal movement of pharmaceutical products from one country to another, where such products already have been legally put on the market by the original manufacturer or its licensed distributors in the first country, is what is defined as parallel importation of pharmaceuticals. Activities related to exports and imports, marketing and sale of parallel imported products are considered as parallel trade. These activities are usually conducted by third parties (parallel traders or parallel importers) who compete with the original manufacturer (or its authorised distributor) to sell their products in the importing/destination country. Thus, parallel trade generally occurs when the same goods are simultaneously marketed by the original manufacturer in different national markets at different prices so that there are arbitrage opportunities that parallel traders can exploit.[1]

At least within the EU, parallel traders do not need a formal approval from the product's original manufacturer or its licensed distributor to be able to import or export. The groundwork for the principle of free movement of goods between EU Member States dates back to 1957 and can be found in the Treaty of Rome.[2] Thereafter, parallel importation is not only legal but also supported by numerous European Court of Justice rulings and by the European authorities as an embodiment of the internal market, one of the basic tenets of the EU.[3]

Pharmaceutical parallel importers are not the main beneficiaries from parallel trade. Indeed, to the extent that there is competition between parallel traders and originators or among different parallel traders, the main beneficiaries are, by all means, the product buyers/consumers in the importing/destination countries who can pay less than they would if originators did not face the challenge from this kind of competition. These consumers range from national governments through social health systems to insurance companies, hospitals, pharmacies and patients.

In the short term, these benefits are reached in two main ways: [4]

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[1]   See Grigoriadis (2014), pp 142.

[2]   See Somorjai (1992), pp. 432-435.

[3]   See *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc. Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.* (case 15-74); *Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler* (*case 187/80*); *Pharmon BV v Hoechst AG* (case 19/84); *Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd (joined cases C-267/95 and C-268/95); Merck, Sharp & Dohme GmbH v Paranova Pharmazeutika Handels GmbH (case C-443/99).*

[4]   See Grigoriadis (2014), pp 146.

a) Through the supply of less expensive medicines by parallel importers. These are usually referred to as **"direct savings"**; and

b) Through the creation of intra-brand competition conditions between the original manufacturers (or authorised distributors) and independent traders of pharmaceutical goods. This competitive pressure leads to reduction in prices of medicines sold by manufacturers or authorised distributors. These are referred to as **"indirect savings"**.

The potential for savings through parallel trade is in principle very large, given the enormous amount of expenditures on pharmaceutical products and the significant spreads between national markets for the same product. Hence, it is not surprising that much attention has been devoted to this subject over the last two decades.

This study further contributes to the empirical assessment of the savings generated by parallel trade, particularly in relation to indirect savings, which have received less attention in the economic literature. Moreover, we follow a more ambitious approach considering not only a small sample of products or quantifications based on anecdotal cases but rather on the analysis of thousands of products for the German and Swedish markets.

Besides this introduction this report is structured as follows:

▪ Section 2 provides a review of the national regulatory frameworks, including reimbursement rules and expenditures; licensing evaluation, pricing mechanisms, and other regulatory instruments.

▪ Sections 3 and 4 present a discussion about parallel trade of pharmaceutical products in the EU and the empirical analyses that have been conducted so far, including quantifications of direct and indirect savings.

▪ In Section 5 we estimate indirect savings for Germany, after discussing its pricing and regulation framework.

▪ In Sections 6 the same analysis is conducted for the Swedish market.

▪ The last sections conclude and list the literature used in this document.

2. National Regulatory Frameworks

2.1. Reimbursements and expenditure

Statutory health law and the national health care system play a major role in most EU countries. For instance, all **Swedish** citizens benefit from publicly funded health care. Nonetheless, despite widespread insurance coverage, patients in this country are charged for visiting general and specialist practices or for hospitalisation, although payments are capped to a yearly out-of-pocket expenditure of SEK 1,100 (≈ EUR 107).[5] Prescription medicines are subject to similar user charges. These are funded by the patient up to reaching an annual amount of SEK 1.100 (≈ EUR 107).[6] Afterwards, health insurance shares the expenses with the patient, gradually decreasing the user fee up to a SEK 2,250 (≈ EUR 219) cap.[7] From that point onwards, prescription drugs become free of charge for the patients.

The arrangement of health care in **Germany** is slightly different, resulting from the legal framework and a clearer division between the public and the private sector. The difference between statutory and private health insurance lays in the rules for funding and payment. For instance, in the case of statutory health insurance, the contributions depend on the patient wage. Thus, according to current regulation, unemployed people or those earning below EUR 59,400 per year are covered by statutory health insurance. Employees earning above that threshold, or self-employed and civil servants, can choose between statutory and private insurance coverage. In the case of private insurance, contributions are based on insured benefits, age and individual pre-existing health conditions, as well as possible risks (e.g. relating to occupation or place of residence).[8] Patients covered by statutory health insurance benefit from advantageous rules regarding out-of-pocket expenses for prescription drugs. The users are charged 10% of the retail price of the medicine. This fee is bounded by a minimum of 5 EUR and a maximum of 10 EUR. However, it never exceeds the actual price of the product[9] so that sometimes the minimum of 5 EUR is not reached. Moreover, there are caps on the overall yearly expenses for medicines so that patients never spend more than 2% of their total household gross income. In case of chronically ill patients, this cap is reduced to 1%.[10] Even if health insurance is mandatory and covers almost all citizens in Germany, only 88% of people are covered by the statutory health insurance. Private funds cover 10% of the population, which compared to Sweden is considerably higher. The remaining 2% are ascribed to special schemes.[11]

Publicly funded pharmaceuticals impose a substantial pressure on the national budget. Figure 2.1. shows pharmaceutical public expenditures in Sweden and Germany as a share of gross domestic product, compared to the European average. The government expenditure on

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[5]   1 EUR ≈ 10,25 SEK.

[6]   See OECD/European Observatory on Health Systems and Policies (2017b), pp.6-7.

[7]   See Dental and Pharmaceutical Benefits Agency (2017a).

[8]   See OECD/European Observatory on Health Systems and Policies (2017a), pp. 7. For current limit for mandatory insurance see Bundesministerium für Gesundheit (2017), pp. 18. For an overview of the relevant factors in the calculation of private health insurance contributions see Simon (2017), pp. 139-144.

[9]   Bundesministerium für Gesundheit (2017) pp. 114.

[10]   See Bundesministerium für Gesundheit (2017), pp. 124-125.

[11]   See OECD/European Observatory on Health Systems and Policies (2017a), pp. 7.

medicines in European countries oscillates around 1% of Gross Domestic Product, which can be considered a significant contribution. As can be seen, German expenditures are permanently above the European average level and this difference has grown over time. Swedish values have remained stable and below the European average.

Figure 2.1. Public expenditures on pharmaceuticals (and other medical non-durable goods) as percentage share of GDP, years 2000-2016
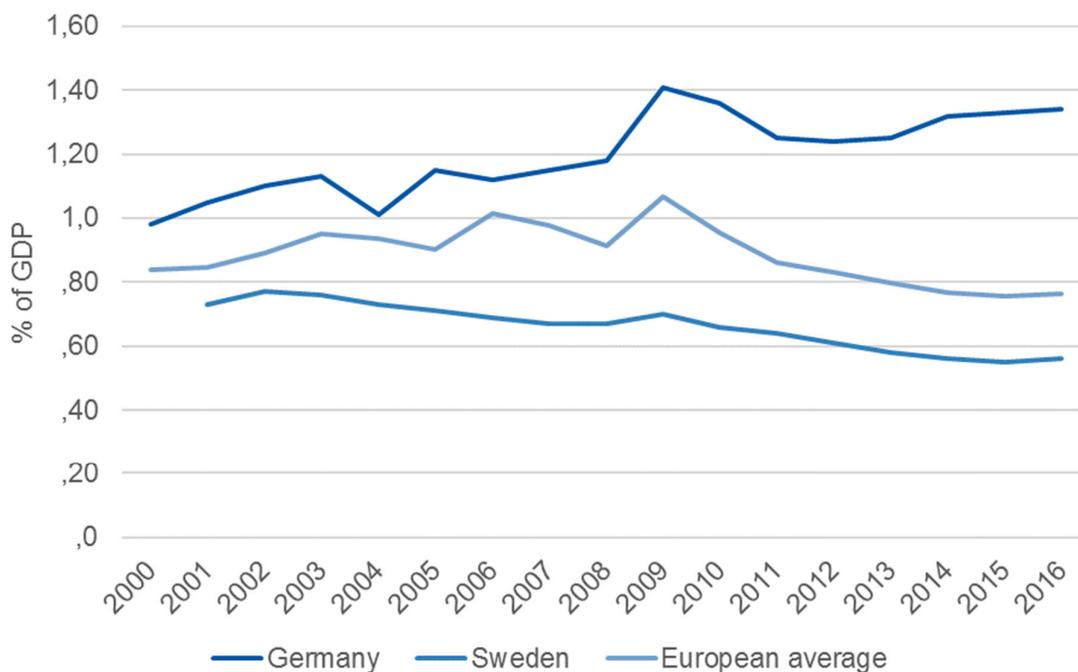
Source: NERA-presentation based on Eurostat "Expenditure for selected health care functions by health care financing schemes" table.

A similar trend can be observed when considering per capita values. As can be seen in Figure 2.2, Swedish per capita expenditures stand at around 250 EUR per person; which is close to the European average. In contrast, per capita expenditure in Germany has increased significantly over the considered time frame, almost doubling its value from 2000 to 2015.

Figure 2.2. Public expenditures on pharmaceuticals (and other medical non-durable goods) as EUR per capita, years 2000-2015
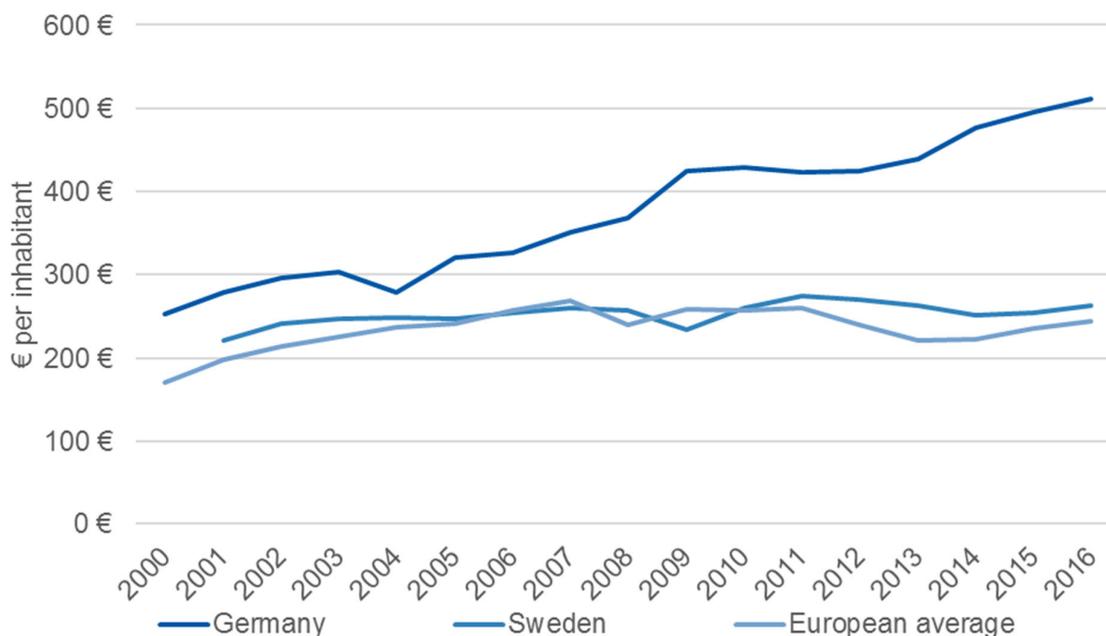
Source: NERA-presentation based on Eurostat "Expenditure for selected health care functions by health care financing schemes" table.

These price evolutions can be explained by various factors, such as the different regulatory frameworks. Although the analysis of the reasons behind such developments in public expenditures on pharmaceutical goods is out of the scope of this report, it shows the importance of regulatory control of the pharmaceutical market. Indeed, decision-making authorities are determined to apply various regulations and restrictions to pharmaceutical companies in order to control their expenses. These range from licensing procedures, through different kinds of Health Technology Assessments (HTA),[12] to pricing and reimbursement controls. These instruments have a significant impact on the dynamics of the pharmaceutical market not only within one country, but also across different Member States.

There are numerous publications concerning regulations in European markets already.[13] Thus, in the following sections we discuss only those that may be relevant to conduct and accurately interpret the results of our analyses, namely the quantification of indirect savings.

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[12]   Currently, a proposal by the European Commission to harmonize HTA at EU-level is discussed. This could be an avenue leading to more price convergence for pharmaceuticals in the EU. See European Commission (2018).

[13]   See Busse, Panteli, & Heschke (2015) and Panteli *et al* (2016).

## 2.2.   Licensing and post-licensing evaluation

Within the EU, pharmaceutical manufacturers must apply for marketing authorisation for their products by submitting registration dossiers, which are further subject to scientific assessments by the corresponding authorities.

Consistent with the single market concept -one of the fundamental objectives of the EU- there is a compatible regulatory approach across Member States to ensure the availability of high quality, safe and therapeutically effective pharmaceuticals evenly across the European market. The authorities have thus developed a system of procedures at the national and international level, namely centralised/decentralised procedures and mutual recognition rules, that vary according to the complexity and reach of the respective authorizations. Depending on the product specification and individual strategy, manufacturers can choose one of the listed proceedings.[14]

The second stage, after the introduction of the pharmaceutical products to the market, includes the so-called post-licensing evaluation (PLE) process. Whereas market authorization focuses on product safety, quality and efficacy, the main goal of PLE is to assess the benefits or additional benefits regarding, for instance, life extension and side effects of a product in comparison with alternatives such as other medicines, non-pharmaceutical therapies or even the absence of therapy. This is generally referred to as Health Technology Assessment (HTA). On the ground of post-marketing evaluation results, the authorities can make more accurate decisions regarding coverage, pricing and reimbursement of new medicines within the individual statutory health system. Thus, the purpose of the PLE is to facilitate and support this decision-process.[15]

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[14]   See European Medicines Agency (2014), pp. 2.

[15]   See Panteli, Eckhardt, Nolting, Busse, & Kulig (2015), pp. 2.

Figure 2.3. Stages of the authorization process for new medicines in EU countries

Market authorization
- The main goal is to ensure product safety, quality, and efficacy
- Standardised rules on the EU level

Post-licensing evaluation
- The main goal is to set pricing, coverage requirements, and reimbursement rules for the new medicine
- It is a differentiated process, with each country setting its own rules
- Cost-benefit analyses play a major role
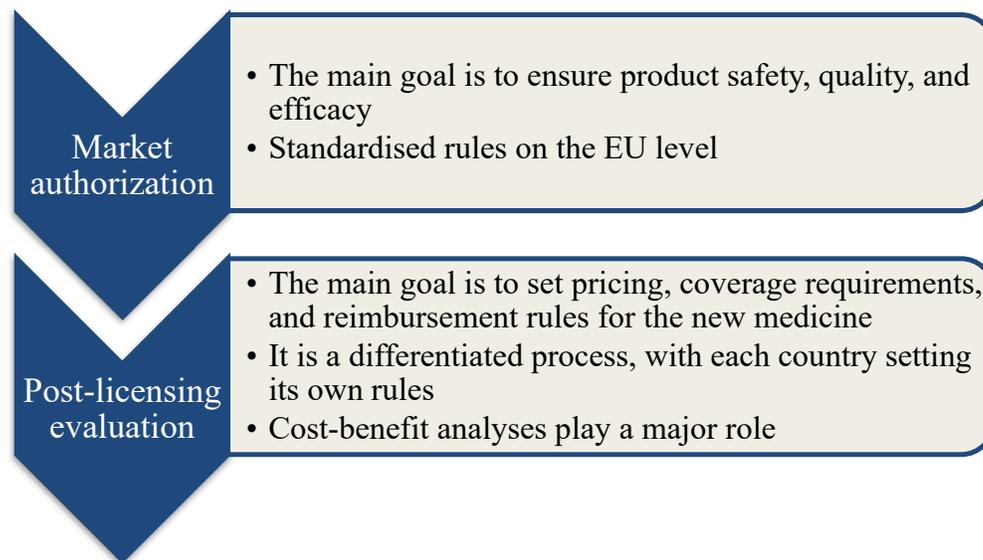
Source: NERA-presentation.

Each national authority is responsible for setting up the scope and carrying out the evaluation within its own health system. However, every country has different specifications and applies different approaches, which has led to the recent proposal by the European Commission to harmonize the evaluations.[16] Some countries focus mostly on the core health benefits or the additional health benefits of the new medicine. Others, however, consider further aspects. Not only ethical, social and organisational implications are of importance, but also the cost-benefit aspects, which contribute to the final appraisal of the submitted dossier. Thus, post-marketing evaluation in European countries can be categorized in two subtypes:[17]

a) **Evaluation with pre-determined price**: pharmaceutical companies submit an application dossier along with the proposed price for the new product. Responsible authorities then examine the application with the aim of assessing if refund for that medicine can be justified, considering its price and efficacy. Such approach can result in a situation where the medicine under consideration provides additional health benefits compared to alternative therapies but does not fulfil the cost-efficiency requirements and thus may be rejected from the reimbursement list. In such case manufacturers need to repeat the process with an adjusted proposal;

b) **Evaluation without pre-determined price**: the assessment of the submitted applications aims to uncover benefits or additional benefits of the considered medicines independently of the proposed market price. The evaluation results become the foundation of future considerations regarding the maximum reimbursement price

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[16]　See European Commission (2018).

[17]　See Zentner & Busse (2011), pp. 27-30.

choice or negotiations between the responsible authorities and pharmaceutical companies concerning the publicly funded price.

The post-licensing evaluations and their outcomes do not only affect pricing and reimbursement decisions, but also the common access to the pharmaceutical products, which is not taken for granted even if the considered medicine is or could be available for sale. This is so because in most European countries new pharmaceuticals are not reimbursed by the statutory health insurance until the PLE is completed. According to EU regulation, the evaluation and reimbursement decision process can take up to 90 or in some cases even 180 days, which in turn corresponds to the period in which certain patient groups have limited or banned access to the medicine. In reality, the actual access to the reimbursed medicines is often delayed beyond that time range, which further accentuates this problem.[18]

2.3. Pricing mechanisms

One difference between pharmaceuticals and other marketable products is that national authorities use regulations to influence prices, such as setting maximum sale prices of medicines. Such an intervention aims precisely to safeguard the budget of the social health systems, which usually covers the largest part of the cost of such products. Since each Member State has the freedom to set its individual policies, there exist differences in the degree of involvement and in the regulatory approach to the pricing of medicines. As a result, price levels of pharmaceuticals vary across the Member States.[19] Thus, unlike other products, it is not always possible to practice free pricing in the pharmaceutical markets or, if formally allowed, in reality the price setting is affected by certain regulatory constraints.

Regardless of the countries' regulations, there is also a strategic dimension that might lead pharmaceutical companies to charge different prices across different EU countries. For products with high sunk or fixed costs (such as R&D for medicines), a profit maximizing strategy from a manufacturer aiming at recovering those costs might well be the setting of differentiated prices, i.e., charging less to consumers with a lower willingness to pay (because of budget restrictions, for instance). If pharmaceuticals were to set a single price for a product across all countries, their profits would be lower since highly sensitive consumers/countries might opt not to purchase. Thus, charging lower prices in those cases would add additional revenues/profits.

It is important to note, though, that the willingness or availability to pay of a country is specific to the product in question, i.e., in general there are no countries with low willingness to pay for all products, but this depends on the product. Thus, although prices tended to be lower in Mediterranean countries in the past, and, therefore, trade flows tend to go from south to north, this is not the case for many medicines. In fact, the pattern has reversed in recent years, with more than 50% of all imports now originating in northern countries.[20] Thus, whenever someone

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[18]   See Panteli *et al* (2016), pp. 20-22.

[19]   See Grigoriadis (2014), pp. 149.

[20]   EAEPC study on Trade Flows, to be published.

refers to importing and exporting countries, or source and destination countries, this is always specific to the product.

Whereas post-licensing evaluation determines whether a medicine is to be added on a positive reimbursement list, some European countries allow the pharmaceutical companies to sell their medicines at unregulated prices and reimburse them even before the PLE process is over.[21] If the reimbursement decision turns out to be negative, the authorities have no more incentive to intervene in the price setting. In such case the pharmaceutical companies can set the prices freely, but patients must then fully absorb the cost until the product is reassessed and eventually added to the reimbursement list.

If the outcome of the post-licensing evaluation is that the product is ready for addition to the reimbursement list, policy-makers decide over reimbursement levels and, as in case of certain groups of medicines, often become actively involved or even take over the control of price setting. The choice of a proper price level is based on a set of different criteria. For instance, reference pricing is a common tool used for price selection whereby the price for a new product is determined by comparing it to other similar or chemically identical products that are already available in the market.

There are two different types of reference pricing methodology commonly used by the authorities in EU countries. The first one is the External Reference Pricing (ERP), which is used mainly for price selection for innovative medicines. In this case, a selection of reference markets is made, and an estimation of a reference price is derived from the prices of identical products in a group of selected countries where that product is already commercialised. This method of price level estimation is often used as a supporting or even as a main instrument during pricing negotiations between regulatory authorities and pharmaceutical companies.[22] The ERP approach, however, needs an accurate assessment of the differences and similarities across the markets that have significant influence on the pharmaceutical prices to ensure appropriate price benchmarking. In this respect, it is more convenient to consider similar markets as references. The methodologies and rules applied to the estimation of the reference prices are however neither identical across countries nor always completely transparent.[23] In this regard, it is often complicated to fully comprehend the use and implications of the ERP criterion.

Furthermore, even if the ERP is not applied by the authorities in one Member State, this does not necessarily exclude its possible impact on the price levels in that country. To some extent, pharmaceutical companies have the means to steer the reference price by, for example, implementing launch sequence strategies[24] or by maintaining high prices in the countries used as reference markets in order to be able to negotiate higher prices in other countries.[25] Thus,

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[21]   For examples see Vogler & Martikainen (2015), pp. 352-353. Note that although manufacturers in mentioned countries can set the prices freely, the respective authorities use other regulations that indirectly restrict the producers' pricing strategies.

[22]   See Kanavos, Fontrier, Gill, & Kyriopoulos (2017), pp. 15-16.

[23]   See Organisation of Economic Co-operation and Development (2008), pp. 102-103.

[24]   See Rémuzat *et al* (2015), pp. 9.

[25]   See Leopold *et al* (2012), pp. 40.

when considering ERP, one should not only assess its application inside but also outside of the analysed market, to fully account for its consequences.

The second type of reference pricing is based on products sold within the same country (Internal Reference Pricing - IRP). This reference is often used for medicines that have been categorised as reimbursable but are not truly innovative, to the extent that there are similar therapies available on the national market. Thus, some characteristics may allow to compare these pharmaceuticals in terms of either innovation degree or therapeutic qualities to other, already available products.[26] In such case, the responsible authorities should make sure that rules and methods used to assign products to the comparator groups are precise and reflect real similarities between the products. This task is not as straightforward, as it also involves weighing the value that each of the unique products within the comparator group has and the differences between these medicines.[27]

Besides reference pricing, some policy makers rely also on the therapeutic value of the considered medicines. The so-called *value-based pricing* method is a well-known concept used also outside the health care sector. Its aim is for the price to reflect the true value that the product brings about to the consumer. In the health sector particularly, the value is defined by health benefits for patients and for society as a whole. The determination of the value can only result from an evidence-based pharmaco-economic assessment of the considered medicine.[28] Furthermore, that value-based pricing might also be a result of different techniques of post-licensing evaluation conducted by most EU member states.

2.4.   Reimbursement process

The implicit result of post-licensing evaluation is the selection of reimbursable medicines made by respective authorities in each of the Member States. This decision is, as already mentioned, based on an evidence-based medical, pharmacological and at times economic evaluation.

Regardless of the specific health care system, in general there are two kinds of reimbursement lists. A positive list includes medicines that are bound to be publicly funded. On the contrary, a negative list contains pharmaceutical products that are explicitly excluded from public funding. In most European countries, the decision is made with respect to a positive list.[29] This means that only products included in such a list are reimbursed while the rest must be fully covered by patients themselves. Yet, in some of the European states pharmaceutical products are generally reimbursable unless they are included in the negative list. There are some Member States that use both positive and negative lists.[30]

Medicines qualified for reimbursement are not necessarily fully covered by public funds. Depending on the health care policies and the classification criteria, patients in some countries

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[26]   See Panteli *et al* (2016), pp. 32-33.

[27]   See Organisation of Economic Co-operation and Development (2008), pp. 104.

[28]   See Paris & Belloni (2013), pp. 12.

[29]   See Busse, Panteli, & Heschke (2015), pp. 28-29.

[30]   See Panteli *et al* (2016), pp. 40.

are subject to out-of-pocket payments, as already explained. Furthermore, some authorities apply different co-payment rules depending on population groups (based on, for example, age or financial situation). Finally, these co-payments mostly take the form of a percentage of the price. Some systems also use fixed fees or deductibles or even combinations of the three basic forms of co-payments.[31]

2.5.   Other regulatory instruments

There are numerous other regulatory mechanisms used by European Member States that also have significant influence on the price levels of pharmaceuticals in Europe.

One of the most common instruments to decrease price levels of pharmaceuticals are **rebates and discounts**. In general, rebates and discounts are subject to negotiations or tendering procedures between public funds and pharmaceutical companies and are often not disclosed publicly. The concept behind is to share the risks and financial responsibilities linked to the introduction of new medicines. Depending on the country, these measures are broadly applied on both treatment sectors (hospital/in-patient and pharmacy/out-patient) with few exceptions where it is applied only to the in-patient sector or not applied at all. Discounts and rebates can also take different forms, like price reductions, bundling, price-volume or risk-sharing agreements, etc.[32]

A further measure that drives down pharmaceutical prices and allows for cost-savings is **price freeze**. In such instance, authorities are able to define time periods within which manufacturers are not allowed to increase prices for certain pharmaceuticals. Another possibility in the scope of price freezes are obligatory price reductions for a certain period of time, that are to be granted to the payers by the manufacturers.[33]

Finally, **parallel trade** is also an important cost-saving measure to the extent that many authorities apply regulations that encourage and support it. For instance, in some countries pharmacies are obliged to proactively inform patients about availability of relevant imported medicines as alternatives to the originator products. Other examples of policies supporting parallel imports are the requirements for pharmacies to stock certain amount of imported medicines or to dispense them if their prices are below the originator's price.[34] Country specific regulations regarding parallel imports will be further discussed in the following sections devoted to the countries analysed in this report.

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[31]   See Vogler & Martikainen (2015), pp. 349 and Busse, Panteli, & Heschke (2015), pp. 35-37.

[32]   For a more detailed discussion in this respect see Vogler, Zimmermann, Habl, Piessnegger, & Bucsics (2012).

[33]   See Panteli *et al* (2016), pp. 57.

[34]   See Panteli *et al* (2016), pp. 59.

3.   Parallel Trade of Pharmaceutical Products in the EU

Parallel trade originates from arbitration opportunities generated by price differences across countries. The larger the differences between individual medicines' prices, the greater the opportunities for parallel trade. Although the EU have devoted efforts to create a continent-wide single market leading to price convergence across countries (and thus a reduction in arbitrage opportunities), the price levels across national European markets for pharmaceutical products remain heterogeneous for the reasons already discussed:

a) The diversity in prices can result, for instance, from country-specific market regulations related to pricing mechanisms. Whereas some Member States apply rather liberal regulations allowing pharmaceutical companies certain degrees of freedom in their price setting decisions, other national authorities set more conservative pricing policies and restrictions in motion.[35]

b) A further reason for cross-country discrepancies in price levels are the pricing and distribution strategies implemented by the pharmaceutical companies to maximize their profits. These strategies depend on the specific economic situation in each country, particularly the willingness or ability to pay for the products, often related to budget constrains as the main buyers in many instances are governmental bodies that acquire pharmaceutical products for the national health systems.[36] The possession of a patented product by a pharmaceutical company obviously gives it an essential advantage when negotiating the price with the competent authorities of a Member State, or when setting their price levels.

Thus, the underlying reason why parallel imports occur is that independent traders take advantage of price differences across national markets to resell the goods imported in parallel in the market of the importing/destination country (for the specific product) at a price lower than that at which identical or similar goods are supplied directly from the manufacturer or its authorised distributors. In order for the independent traders to have an economic incentive, the price in the importing country must be higher or at least equal to the sum of the acquisition price in the exporting/source country plus transaction costs (usually transport and distribution, repackaging and/or relabelling of the products and authorization fees; and, if applicable, any claw-back tax/scheme or savings targets imposed by law).

Therefore, when the price levels of pharmaceuticals differ significantly across countries, such situation creates an advantageous environment for parallel traders to develop their activities. These involve the selection of not only the products, but also the identification of the two countries between which trade would flow and would allow them to cover their costs and make a profit margin. Obviously, an independent trader is most likely to become involved in parallel trade if he believes that he can resell the imported goods at a price level that is lower than the competing product from the originator (to be able to lure buyers or meet publicly imposed saving schemes/targets) but higher than the costs resulting from exporting the products to that market.

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[35] See Danzon & Chao (2000).

[36] See Danzon, Wang, & Wang (2005).

It is not rare that such opportunities in the EU attract more than one parallel trader, encouraging competition not only between the parallel trader and the original manufacturer in the exporting/destination country, but also among different parallel traders.

Not surprisingly, countries with relatively higher price levels for most products tend to have more parallel traders present than countries with lower prices, although there are some exceptions. For instance, the market shares of parallel imports in the pharmaceutical market between 2003 and 2016 reached on average 8,9% and 14,2% in Germany and Sweden, respectively.[37] Over the years, parallel trade market shares in those countries have been some of the highest across the EU[38], although growth rates and market shares of parallel trade in those countries have taken a dive or lagged in recent years.[39] In 2018, for instance, growth rates for parallel trade overall were +2% and -10% in Germany and Sweden, respectively. This, however, can be the result of lowering prices for mature products in some markets. Nonetheless, various comparative studies have also demonstrated that the price levels of identical products in these countries are still on average higher compared to other European nations.[40]

As already discussed in Section 2, pharmaceuticals cause large expenditures to all types of payers. For instance, public funds in Sweden in 2016 spent over EUR 2,6 billion in pharmaceutical products. This amounts account for 0,56% of national GDP. In Germany, public expenditures on pharmaceuticals and other medical non-durable goods reached over EUR 42 billion, which accounts for 1,34% of national GDP. This represents a *per capita* expenditure of German public funds of EUR 511 per person, whereas for the Swedish government these figures stand at EUR 263.

Out-of-pocket payments by households are not to be ignored. In Sweden, the sum spent by the private payers reached almost the level of public spending: EUR 2,38 billion. In the case of Germany, households spent significantly less than the public health insurances, reaching EUR 7,67 billion. When also taking into account private expenditure, the per capita spending figures for Germany and Sweden add up to EUR 606 and EUR 503 respectively. Figure 3.1. presents a comparison of public and private spending for pharmaceuticals in year 2016.

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[37] According to the EFPIA (2018) report in 2016 the share of parallel imports in pharmacy market sales in the European Economic Area was as follows: Denmark, 25,5%; Sweden, 12,9%; Great-Britain, 9%; Germany, 8,5%; Netherlands, 8,2%; Ireland, 5,4%; Poland, 1,9%; Belgium, 1,6%; and Austria, 1,6%. See EFPIA (2018), pp. 5. On the other hand, pharmaceuticals are exported in parallel mainly from Spain, Italy and Greece. See in this respect Ganslandt & Maskus (2004), pp. 1046.

[38] Calculations are based on the shares of parallel importers as reported by the EFPIA in the annual "The Pharmaceutical Industry in Figures" reports for the years 2005-2018.

[39] See IQVIA presentation (2018).

[40] See in this respect Leopold *et al* (2013) and Vogler, Vitry, & Babar (2016).

Figure 3.1. Public and private share in pharmaceutical expenditures in 2016
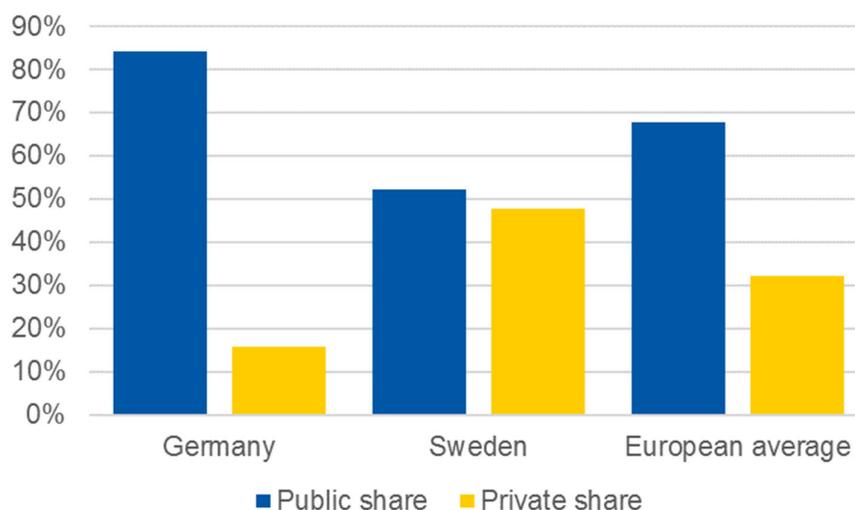
Source: NERA-presentation based on Eurostat "Expenditure for selected health care functions by health care financing schemes" table.

In the light of these data, it is understandable that both public and private payers are very interested in reducing their medicine bill. To the extent that parallel trade induces savings (whether directly or indirectly) or it has the potential to induce even more, this certainly leads to overall improvement of social welfare and must be considered as very positive for the market.

3.1.   Empirical inquiry into parallel trade

The economic impact of parallel imports of pharmaceuticals has been discussed for many years. Numerous researchers have attempted to estimate the effects related to the activity of parallel importers. What is of particular interest to public authorities is to determine whether there is indeed empirical evidence that allows to conclude that parallel trade leads to savings.

In this regard, for instance, West & Mahon (2003) were the first to conduct an international study to try to quantify direct and indirect savings in the United Kingdom, Germany, Netherlands, Sweden and Denmark. Using a sample of top selling products, as well as a random sample of 150 products, the researchers estimated around EUR 635 million of direct savings in 2002 for national social insurance institutes, patients and pharmacists across all of the tested countries. Moreover, based on Swedish data, they have also found statistical evidence proving that competition from parallel importers lowered prices of originator's products.

However, other studies, such as that conducted shortly after by Kanavos, Costa-i-Font, Merkur, & Gemmill (2004), produced different results. Using a sample of 19 products that covered 21% of the whole market, they estimated only EUR 44,8 million of direct savings in the period 1997-

2002 (around EUR 100 million including the clawback effect)[41] for systems of social health insurance. On the other hand, they found that parallel traders including importers and resellers generated significant profits (about EUR 704 million; EUR 648 million including the clawback effect) from their parallel trade activities. Since this study included Norway in the sample, the difference between this and the study conducted by West and Mahon is even more significant.

Over the years, other studies (as those we analyse in Section 4.2 below) have tried to quantify direct and indirect savings, offering different results. Thus, the question as to how much savings parallel trade generates remains to some extent unanswered, although there is broad strong feeling that parallel trade does indeed exert a competitive pressure and results in lower prices.

Besides the question regarding the extent of these savings, it is also relevant to ask whether the benefits from parallel trade extend to patients and/or national governments as opposed to, for instance, other agents involved in the supply chain, particularly wholesalers (parallel traders) or pharmacies.[42]

There is also the sense that this question has not yet been fully answered by economic experts and, as a result, there are no safe findings that could be used by legal commentators. For instance, in the Opinion of Advocate General Jacobs in *Syfait and others*, it is not possible to argue safely that parallel trade of medicines has, in the short term, significant benefits for end consumers and purchasers of pharmaceutical products in the Member States. He accepts that it seems reasonably clear that parallel trade always implies at least small direct and indirect savings for purchasers and consumers and that the amount of these benefits for patients and national governments depends on how the distribution chain of medicines (manufacturers, parallel traders, pharmacists, etc.) is regulated and the mechanism devised to bring benefits to the final consumers. In this sense, it is not surprising that Member States have imposed various policies to assure that the profits from parallel trade are shared between parallel traders, buyers and consumers, in particular national governments and patients.[43]

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[41] The clawback is a mechanism allowing the insurance funds to enforce pass on of discounts received by pharmacies from wholesalers back to them in form of savings. See in this respect Kanavos, Costa-i-Font, Merkur, & Gemmill (2004), pp. 64.

[42] For instance, in the opinion delivered by Advocates General Jacobs and Ruiz-Jarabo Colomer in cases *Syfait and others* and *Sot. Lélos kai Sia*, respectively, he has stated that:

Sources: Opinion of Mr Advocate General Jacobs on *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE (case C-53/03)* and opinion of Mr Advocate General Ruiz-Jarabo Colomer on *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE Farmakeftikon Proïonton, formerly Glaxowellcome AEVE (joined cases C-468/06 to C-478/06).*

[43] See Grigoriadis (2014), pp. 148.

4. Savings from Parallel Trade

Parallel trade of medicines has existed in Europe for over forty years, since its recognition as a legitimate practice during the inception of the EU Common Market, in line with its founding principles of free movements of goods, services and people, and facilitated by the regional exhaustion of intellectual property rights. It has grown significantly in size and importance over the years, together with the evolution and extension of the single European market.

The European Commission, EU case law and several economic studies agree that parallel trade encourages competition in the market, ostensibly generating economic savings as it:[44]

   a) Plays a positive role in keeping drug prices low;

   b) Assists EU Member States with their healthcare budgets; and

   c) Offers patients access to cheaper medicines.

This competition between the domestically sourced products and the imported medicines exerts downward pressure on prices, generating savings in markets where otherwise there would not be any competitive force, particularly for patented products for which inter-brand competition is not possible.

Consequently, this practice is encouraged by governments and regulators.[45] Indeed, as it has been already mentioned, some administrations have been keen to reform their national legislations to stimulate parallel imports of pharmaceutical products and let the savings play an important role in containing the upward spiralling public healthcare bill in many European countries. In particular, this has been the case in countries historically considered importing/destination countries, such as the United Kingdom, Sweden, Denmark, Germany and the Netherlands, although lately countries such as Lithuania have also changed their rules to stimulate parallel imports.

The main parties benefitting from parallel trade are:[46]

   a) **Consumers of pharmaceutical products**. The importing/destination Member State usually retains the largest share of economic savings generated by parallel trade, thanks to price reductions from parallel imported medicines compared to the originator's products;

   b) **Hospitals and Pharmacies**. In order to administrate or sell medicines to final consumers, hospitals and pharmacies ought to purchase the product in markets where manufacturers could enjoy significant market power. Parallel trade, however, offers a cheaper alternative source of supply, bringing down prices and, consequently, generating savings for hospitals and pharmacies. Besides, in the absence of parallel

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[44] See Abott (2007), pp. 7.

[45] Restrictions of parallel trade of pharmaceuticals are monitored by the EU and national competition authorities and there have been decisions fining companies who restricted parallel trade in medicines. For a recent overview see (European Commission (2019), pp. 12 and 26.

[46] See EAEPC (2011), Annex III.

traders, pharmacies in several Member States would not be in a position to sustain government policies aimed at decreasing the price of medicines;

c) **National Health Care systems**. Member State governments and statutory health insurers are also positively affected by parallel trade in their national markets. This is largely due to the collective agreements with parallel importers that many national governments have signed, establishing reimbursement price limits or clawback clauses with lower reimbursement rates for imported products, which generates increased savings for health care systems thanks to its subsequent effects.

As also mentioned previously, the short-term savings and benefits generated by parallel trade in pharmaceuticals are of two types: **direct** and **indirect savings**. Direct savings result from the difference in medicine prices between originator's products and imported/parallel products. These savings can be directly quantified by multiplying the price difference by the volume of parallel imported drugs sold in a given period.[47]

Figure 4.1. Graphic depiction of direct savings
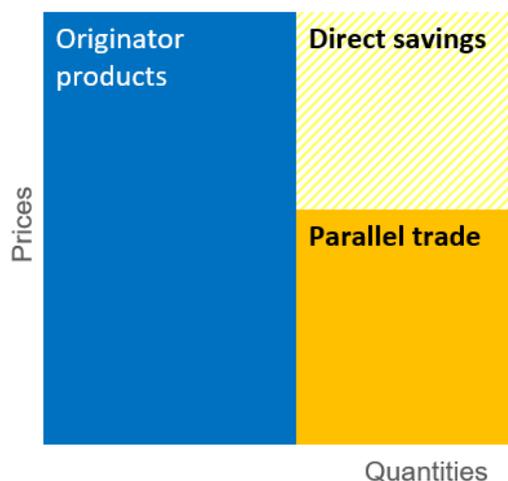
Source: NERA-presentation.

Direct savings can be reached, for instance, through reimbursement schemes, since these schemes usually provide incentives to purchase cheaper products. This benefits patients and/or governments and, consequently, taxpayers. Depending on the reimbursement arrangements, savings would benefit patients directly (e.g. when medicine co-payment is related to price) or indirectly through a reduction in third party drug expenditure, allowing resources to be used for other purposes in the interests of end users, or simply translating the savings into lower health insurance contribution rates.

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[47] This methodology implicitly assumes that there is no increase in drugs consumptions when cheaper products become available. This is a reasonable assumption though, since the price elasticity of medicines are usually low, partly because the purchasing decisions are not made by the patients (the consumer) but by their doctors. Besides, patients usually do no bear the full price.

Indirect savings result from price concessions made by originators, i.e. reduction in prices that original manufacturers agree to as a response to potential or actual competition from parallel importers. These savings can be calculated as the amount by which manufacturers decrease prices, in relation to a situation with no parallel trade, multiplied by the volume of medicines sold in the market during a given period.

Figure 4.2. Graphic depiction of indirect savings
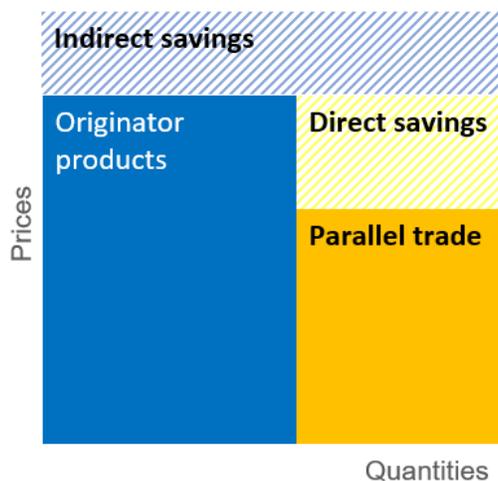
Source: NERA-presentation.

The estimation of indirect savings entails some assumptions regarding how prices would have evolved in the absence of the parallel trade, and on the causal link between parallel trade and changes in the prices of the originator products. This is necessary since the "counterfactual" price on which the calculations are based is not observable and, therefore cannot be measured directly.

Indirect savings from the parallel trade of pharmaceutical products arise from two main sources:

a) **Competition** from parallel imported products leads to price decreases by the originator, or at least lower price increases. As has been explained already, parallel trade only arises under the condition that the pharmaceutical product in question in the exporting/source country has a lower price than that of the originator's equivalents in the importing/destination country. To the extent that manufacturers have monopoly power over their (patented) drugs, it is evident that parallel trade is a way to counterbalance this power when setting prices;

b) **Potential competition** from parallel traders also leads manufacturers to lower their prices in the importing/destination Member States. Parallel imported medicines have shown to have "stabilizing effects" on the price of originator medicines in importing/destination countries, since manufacturers often choose to reduce the domestic price to a level at which it is no attractive for parallel importers to enter the market. Thus, indirect savings emerge because of the threat of potential competition. Therefore, it is not even necessary to observe the presence of parallel trade in an

importing/destination country for it to have a real effect on the originators' price; the threat of competition might be enough.

4.1. Empirical challenges in estimating direct and indirect savings

As we have pointed out, there have been a number of studies that have tried to estimate direct and -to a lesser extent- indirect savings. This is partly because, as we have also stated above, direct savings are simpler to quantify as they require no estimation of what originator prices would have been in the absence of parallel trade. These studies have arrived at different results.

It is very important to note, however, that the figures quantified in these studies may represent only a fraction of the potential savings from parallel trade, to the extent that there have often been restrictions imposed by pharmaceutical companies in exporting/source markets in order to prevent or hinder parallel trade and reduce the competitive pressure from parallel traders in the importing/destination markets.

These practices by manufacturers and/or authorised distributors have not always been compatible with the Court of Justice's case-law and/or Articles 101 and 102 of the Treaty of the Functioning of the European Union (TFEU). Thus, they have been sometimes subject to investigation by competition authorities. These restrictions include, for instance:

- **Indirect bans on parallel exports**. The clear incompatibility of contractual clauses imposing direct bans on parallel exports under Art. 101 of the TFEU has forced manufacturers to rely on disguised prohibitions on parallel exports to restrict parallel trade between the Member States. Such prohibitions have arisen from strategies aiming to discourage authorised sellers of a product in a specific Member State to engage in parallel exports of the product to other Member States. In this respect see, for instance, *Sandoz prodotti farmaceutici SpA v Commission of the European Communities (case C-277/87)*; *Bayer AG v Commission of the European Communities (case T-41/96)* and *Bundesverband der Arzneimittel-Importeure eV and Commission of the European Communities v Bayer AG (joined cases C-2/01 P and C-3/01 P)*;

- **Refusal or restriction of supply to parallel traders.** A strategy applied by pharmaceutical companies in their attempt to hinder parallel trade is the refusal or the restriction of supply to wholesalers, with the intention of avoiding supply in excess of domestic demand. This has often led to a system of quotas set by manufacturers, who determine how much volume they will supply to wholesalers in the exporting/source country, leaving little to no margin for parallel exports. In this respect see, *Syfait and others (case C-53/03)* and *Sot. Lélos kai Sia (joined cases C-468/06 to C-478/06)*;

- **Dual Pricing Systems.** Another strategy that is adopted by pharmaceutical companies in their attempt to hinder parallel trade is the so-called "dual pricing systems". Within the framework of a dual pricing system, a pharmaceutical company operates a distinction between, on the one hand, the prices charged to wholesalers reselling its products to domestic pharmacies or hospitals for (reimbursable) domestic end-use and, on the other hand, prices charged to wholesalers exporting the products (parallel traders). Specifically, in the context of a dual pricing system, the medicines that are not meant for consumption on the domestic market and that will not be reimbursed by social security or other public funds are charged at higher prices by pharmaceutical companies.

In this respect see, for instance, *GlaxoSmithKline Services Unlimited v Commission of the European Communities (case C-501/06 P)* and *Commission of the European Communities v GlaxoSmithKline Services Unlimited (case C-513/06 P)*;

▪ **Marketing Authorisation Withdrawal**. In other instances, the request is made by a pharmaceutical company for the withdrawal of its marketing authorisation for a medicine in the exporting/destination Member State in order to stop the exporting of its products. In this regard, see, for instance, *Decision 2006/857/EC* of the European Commission (2006); *AstraZeneca AB and AstraZeneca plc v European Commission (case T-321/05)* and *AstraZeneca AB and AstraZeneca plc v European Commission (case C-457/10 P)*.

Price convergence has been also quoted as another strategy to prevent parallel trade. That is, by increasing the price in the source/exporting country and reducing it in the destination/importing country, the incentives to profit from this activity are clearly reduced. It is not clear, however, if these can be considered anticompetitive practices or if this can just be the consequence of parallel trade, particularly because manufacturers react to parallel trade competition by setting similar -and not differentiated- prices across all Member States, which could be a profit maximizing strategy given the competition they face.

Thus, even though the savings from parallel trade are not very large, the potential savings could be much more significant if these restrictions to parallel trade did not exist and parallel traders were allowed to export larger volume of products or at least be a credible competitive constraint on originators in importing/destination markets.[48]

4.2.   Studies quantifying the savings from parallel trade

With the above caveat, we summarise below the different studies conducted so far that have estimated indirect savings. Some of these studies have analysed how direct and indirect savings have evolved over time in some countries (for instance Sweden), the factors that have led to their decline (such as price convergence, restricted supply in exporting countries, etc.) as well as the potential for savings if more parallel trade was possible.

▪ West & Mahon (2003) were the first to conduct an international study to try to quantify savings in the United Kingdom, Germany, Netherlands, Sweden and Denmark. Based on information for the top-selling products plus a random sample of 150 products, this study measures direct savings for the period 1997-2002 and conducts broad estimates of indirect savings. Indirect savings were analysed under two different methodologies: a) using a time plot analysis where domestically-sourced goods and their parallel-distributed competitors were assessed, and b) a statistical analysis, for which competition effects were identified by separating products facing parallel trade competition from those that did not, and examining price changes. Results from the first analysis show that companies behaved differently when facing parallel trade competition: some engaged in price competition to drive parallel trades out of the market while others seemed to have lost large market shares to parallel trade

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[48]   As we have also already pointed out, for the benefits to be realized it is not even necessary for parallel traders to enter the importing/destination market but just to be credible potential competitors that could enter, which means that they must have the incentives and the capacity to supply the product.

competitors. The second statistical analysis provides robust evidence that the prices of products subject to parallel trade competition exhibit a distinct pattern, as originators reduced their prices or at least froze them. In particular, for Denmark, average price changes for patented drugs between 1997 and 2002 rose 2.2% for those products facing no competition, versus a 13.0% fall for those facing parallel trade competition.

- Ganslandt & Maskus (2004) assess some policy issues regarding parallel imports of brand-name pharmaceuticals in the European Union. The authors developed a simple model in which an original manufacturer competed in its home market with parallel traders. Their model suggests that, for small costs of trade, the original manufacturer would accommodate the import decisions of parallel traders and that the price in the home market fell as the volume of parallel imports increased. Using data from Sweden they found that prices of drugs subject to competition from parallel imports fell relative to other drugs over the period 1994–1999. Econometric analysis found that parallel imports reduced manufacturing prices by 12–19%. There was evidence that this effect increased with multiple parallel traders.

- Enemark, Pedersen, & Sørensen (2006) calculated and updated direct and indirect savings estimates, based on 50 products, for Denmark, Germany, the United Kingdom and Sweden. They found that parallel trade of pharmaceuticals generated in 2004, EUR 24.7 million in indirect savings for patients and health care systems in Denmark, Germany, Sweden and the United Kingdom. The authors developed two analytical methods for estimating indirect savings: a) the first one was a regression analysis for 50 individual products based on price series data. They tested whether parallel trader entry affected the originator price; b) the second method estimated the amount of indirect savings for the full market. The idea was to use a specific product as an indicator of the price level if there had been no parallel imports so that any difference between the originator price and the maximum reimbursable price was assumed to be due to parallel trade competition. This study concluded that indirect savings were significant; standing at EUR 25 million for Denmark and Sweden.

- EAEPC (2011) offers an overview of the monetary savings (both direct and indirect) with a focus on new, developing parallel trade markets: France, Italy, Poland, the Netherlands, Latvia and Ireland; covering the period 2009-2011. The authors suggest that in all of these markets, parallel trade has played an important role in driving down prices of originator medicines. These price reductions have been most visible in Poland and France in recent years, with the two countries posting indirect savings of as much as EUR 22 million and EUR 36 million in 2009, respectively. This is remarkable because those savings have been achieved with only a very small parallel trade market share. Price decreases of originators' drugs due to parallel imports have also been noteworthy in Ireland, where, for instance, in 2010 Pfizer reduced the price of some of its products by up to 47% of the original prices due to competition from cheaper parallel imported products.

- Enemark & Pedersen (2011) constitutes a follow-up of the study undertaken in 2006 by the University of Southern Denmark (Enemark, Pedersen, & Sørensen (2006)). Indirect savings are more explicitly estimated for Denmark and Sweden, and savings were calculated relying on price reductions of originators due to parallel trade competition. The authors concluded that in the Scandinavian markets, indirect savings had increased

since 2004, with these now contributing a larger share to total estimated savings: 46% in Denmark and 36% in Sweden in 2009, compared to 37% and 27% in 2004, respectively.

- EAEPC (2013) is an update of EAEPC (2011). Indirect savings are estimated based on anecdotal evidence of particular products that are extrapolated into other medicines.

- Prognos (2013) estimates direct savings in the German market for prescription drugs in 2013 and 2014, as well as the amount of the potential direct savings that could be realized if market shares of parallel imports were to increase to the level of the top selling products. The estimate of direct savings amounts to EUR 174 million and EUR 222 million for the years 2013 and 2014, respectively. If the market shares of all imported products increased to the level of the top selling products, direct savings would increase up to EUR 229 million and EUR 343 million for both years.

- Méndez (2016) investigates and quantifies the impact of parallel trade in markets for pharmaceuticals based on a structural model of demand and supply using data on prices, sales and characteristics of "Statins", a genre of molecules used in the treatment of high cholesterol in Denmark. The model provides a framework to simulate outcomes under a complete ban of parallel imports, keeping other regulatory schemes unchanged. The results show that both generic firms and original manufacturers would increase their prices if competition from parallel importers were removed. Given the prevailing reimbursement rules, most changes in pharmacy purchase prices would be absorbed by the government.

As one can see, statistical information for indirect savings in EU countries is rather limited.

5. Indirect Savings in Germany

5.1. Regulation and pricing[49]

In Germany, nearly 90% of the population receives health care services through an insurance by one of the roughly 110 Statutory Health Insurance (SHI) funds. Around 9% is exclusively insured by private companies.[50]

The largest share of the healthcare products cost is thus borne by the SHI funds (approx. 74% in 2016). The second largest cost-bearing body are the private households/private non-profit organizations (approx. 14% in 2016). Private insurance funds and employers bear approximately 7% and 3% of the costs (2016 figures), respectively.[51] However, it should be noted that employers pay 50% of the general health insurance contribution rate to the SHI funds.

Free pricing of new medicinal products is currently limited to a short period of time after market launch. Thereafter, a negotiated price kicks in based on the outcome of an early benefit assessment. There are a number of statutory cost-cutting instruments in force though, including mandatory rebates, a quota for generics and parallel imports and fixed reimbursement caps.

Until a few years ago, pharmaceutical companies were allowed to freely set and change the manufacturer's selling price. The Act on the Reorganisation of the Pharmaceutical Market 2011 (AMNOG) still allows for free pricing but only for an initial period of 12 months after the product is marketed for the first time.

For all newly launched pharmaceutical products the benefit assessment is mandatory. The manufacturer has to submit a dossier, which is evaluated by the G-BA or,[52] rather, assigns the evaluation to the independent Institute for Quality and Cost-effectiveness in the Healthcare Sector (IQWiG).

After the G-BA decision on a product's benefit, there are mainly two possible scenarios:

a) If the product has no additional benefit, it is allocated into a group of comparable substances within the Germany's reference price scheme.[53] The price level in this case can be fairly unfavourable for the manufacturer of a newly developed pharmaceutical since the comparator therapy may be a low-priced generic.

Approx. 75% of effected prescriptions are subject to this fixed reference price scheme (*Festbeträge* - FB), which establishes reimbursement caps determined by the G-BA and the GKV-SV for groups of similar or therapeutically comparable substances. The level of the FB is set within the lower third of the price range of the reference group of

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[49] Most of the information in this section comes from Hogan Lovells (2014), pp 13-22.

[50] All SHI funds are represented by the Federal Association of SHI Funds (*GKV-Spitzenverband* – *"GKV-SV"*), a single national head organization.

[51] Calculations based on *Gesundheitsausgaben in Deutschland*, Statistisches Bundesamt (2019).

[52] The head organisations of SHI funds, SHI-accredited physicians and hospitals form the Federal Joint Committee (*Gemeinsamer Bundesausschuss* – *"G-BA"*).

[53] If there is no reference price group, the company must enter into negotiations on the reimbursement price with GKV-SV.

products whilst ensuring that 20% of the prescriptions and 20% of the packages within the group are cheaper or equal to the FB. An exception for this rule applies when all the products within the group are protected by patents. In such a case, the FB equals the weighted average of all the products within the group. The FB are reviewed annually to assure consistency with the current market situation.

If the manufacturer is not willing to cut the price to the level of the reimbursement cap, the exceeding amount must be paid for by the patient if he/she does not want to be prescribed an alternative therapy, which is unlikely since the alternative product would be fully reimbursed by his/her SHI fund. This exerts competitive pressure on pharmaceutical companies to keep prices down so that only a few products have prices above reimbursement caps. In fact, most product prices are below the reimbursement cap and all products that stay at least 30% below the price of the FB are freed from co-payments.[54]

b) If an additional health benefit from the pharmaceutical product is indeed found (*frühe Nutzenbewertung* – NBR), the manufacturer enters into price negotiations with the GKV-SV. In this case, the medication obtains a status of a single-source drug and is covered in form of a reimbursement amount by the German statutory and private health insurance. The reimbursement price is negotiated on the basis of the assessment and the degree of additional benefits and the amount of reimbursement is defined in a process of central discount negotiations between the respective producer and GKV-SV. In case of a dispute, the latter is substituted by an arbitration board. This process is also highly influenced by the actual ex-factory prices (ApU) in other EU countries (ERP, or International Reference Pricing - IRP).

Indeed, ERP is a widely used pricing tool, helping the policy makers negotiate the prices for new medications. Even though many countries base their prices solely on the ERP, German policy makers use it only as a decision supporting information. The reference price baskets strongly vary across countries. Germany includes references from 15 nations.[55]

Moreover, as already mentioned in section 2.2., the ERP can also influence manufacturer's pricing and marketing decisions even if this has no direct application within a country in question. With 17 times, Germany is one of the most referred countries among EU Member States.[56] It is thus understandable that in presence of competition pressure, pharmaceutical companies might consider setting high prices in Germany (or not to decrease them) in order to keep prices up in these other 17 national markets using the price in Germany as a reference.

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[54] The list of products which are freed from co-payments is updated by the GKV-SV every two weeks and can be found at: https://www.gkv-spitzenverband.de/service/versicherten_service/zuzahlungen_und_befreiungen/befreiungsliste_arzneimittel/befreiungsliste_arzneimittel.jsp

[55] See Rémuzat, *et al* (2015) for a detailed description of the External Reference Pricing.

[56] See Rémuzat, *et al* (2015), pp. 5.

5.1.1.   Parallel Imports and rebates

The SGB V[57] encourages parallel imports in Germany. For instance, when dispensing medicines, pharmacists are obliged to replace domestic pharmaceuticals with respective parallel imports if they cost at least 15% or €15 less than the equivalent original product sourced in Germany.[58]

However, dispensing parallel imports can be prevented by domestic pharmaceutical entrepreneurs by the means of individual rebate contracts with SHI funds. Thus, in addition to some mandatory discounts, manufacturers are invited to grant contractual rebates to individual funds.[59]

Usually, SHI funds invite all manufacturers of generic substances to participate in tender procedures bidding rebates. Such a tender procedure is carried out for individual active ingredients. The manufacturer being awarded the contract will have exclusive supply for all patients of this very SHI fund typically for two years; sometimes the exclusive supply is only granted for a specific region whereas a different manufacturer is granted exclusivity in another region.

For innovative substances, this system of tendering and granting exclusivity generally does not apply. However, the regulatory framework provides various incentives for manufacturers of patented substance to voluntarily enter into rebate agreements. For example, pharmacists are obliged to preferentially dispense rebated pharmaceuticals if they are available. Drugs subject to rebate contracts are also, to a certain extent, exempted from the cost-effectiveness test that physicians regularly undergo regarding their drug issuing prescriptions.[60] Also, patients can be exempted from the personal out-of-pocket payments in respect of rebated pharmaceuticals. Rebates may only be granted to SHI funds and private insurers, but not to wholesalers or pharmacies.[61]

5.2.   Empirical analysis

5.2.1.   Data preparation and description

The analysis of the competitive effect of parallel imports on the German market for pharmaceutical products is based on a dataset that contains biannual information on volumes and revenues of medicines that were sold by originators as well as parallel importers in the German market within the period 2011 to 2017. Overall, the raw dataset comprises about

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[57]   The Social Security Code V (*Sozialgesetzbuch V – "SGB V"*) regulates prescription and reimbursement of medicinal products and medical devices for the 90% of the German population which is insured by public sick funds.

[58]   We understand that a new law has recently been passed, making some changes to this system. For products costing less than 100€ at least 15% saving are required; for products between 100-300€ at least 15€ savings; and for products costing more than 300€ at least 5% savings.

[59]   In 2012, rebate contracts covered 65% of all distributed patent-free pharmaceuticals.

[60]   In issuing prescriptions, physicians use certified computer programmes displaying information on rebate contracts of all SHI funds.

[61]   For distributing pharmaceuticals to patients in Germany, manufacturers also sign sales contracts with regional or national wholesalers and can also sell directly to pharmacists and hospitals.

24,200 different medicines that were distributed by parallel importers and about 3,500 medicines that were sold by originators.

The matching procedure to combine the information on parallel imports with the corresponding originator product is based on the classification of groups of interchangeable products that summarizes chemically and therapeutically identical products with similar dosage form and package size. Therefore, we have aggregated volumes and sales revenues of originator products and imported products at the level of interchangeable product groups and years. Whenever we use the term product, we implicitly refer to a group of interchangeable products.

Afterwards, we have computed unit average prices for originator products and imported products (defined as value sales in euros divided by volume sales in units) as well as the market share of parallel imports by product and year. We have excluded all products facing competition from generic drugs.

We ended up with about 1,300 products that were subject to our analyses. Overall, the dataset comprises products with prices ranging from €2 to approximately €20,000. Importers' prices tend to be lower than originators' prices across all products.

At the aggregate level, originators' and parallel importers' revenues experience a steady increase within the period 2011 - 2017. As such, originators' revenues have increased by 93% from about EUR 840 million to more than EUR 1,600 million in the respective time period. Revenues generated by parallel imports have grown by 104% from EUR 132 million to roughly EUR 270 million. Overall, the total market share of parallel imports across all products represented in our dataset appears to be quite stable fluctuating between 13% and 14%.

The following section presents the analyses to assess and identify patterns in the data that are consistent with a pro-competitive effect of parallel imports on originators' prices in the German market for pharmaceutical products.

5.2.2. Correlation between parallel trade and originators prices

This section presents several descriptive analyses aiming at establishing what subset of the dataset shows a clear relationship between the presence and magnitude of parallel trade and originators' prices. Although the competitive pressure from parallel trade can be inferred from economic theory to affect all products, for this exercise we firstly consider those products for which the impact is clearly revealed by a negative correlation between market shares and originators' prices.

The following analyses relate to the correlation between originators' prices and parallel imports. A correlation coefficient is a numerical measure that reflects the size and direction of a (linear) relationship between two variables. The value of a correlation coefficient is always between -1 and +1. A coefficient of -1 (or close to -1) indicates a negative relationship: a change in the value of one variable is associated with a change in the value of the second variable in the opposite direction. A coefficient of +1 (or close to +1) indicates a positive correlation: a change in the value of one variable relates to a change in the second variable in the same direction.

A correlation between variables does not automatically imply that the change in one variable is the cause of the change in the values of the other variable. Hence, while a negative correlation between originators' prices and market shares of parallel imports is consistent with a pro-

competitive effect of parallel imports; this cannot be necessary interpreted as a causal relationship since there may be other factors influencing prices.

On the other hand, a positive correlation between originator prices and the market share of parallel imports does not mean that there is not competition effect since this might, for example, be due to particular characteristics of a medication. Products characterized by an increasing price level on the German market might provide more arbitrage opportunities and therefore be more viable for parallel imports. Similarly, parallel imports may still exert downward pricing pressure if originator prices had increased to a larger extent in the absence of import competition. Consequently, even though a product features a positive correlation, there may well still be a negative causal effect of parallel imports on originators' prices. Indeed, we expect this to be the case.

The graph below shows the distribution of the correlation coefficients between originators' prices and parallel traders' market shares of each product.

Figure 5.1. Frequency Distribution of Correlation Coefficients (Germany)
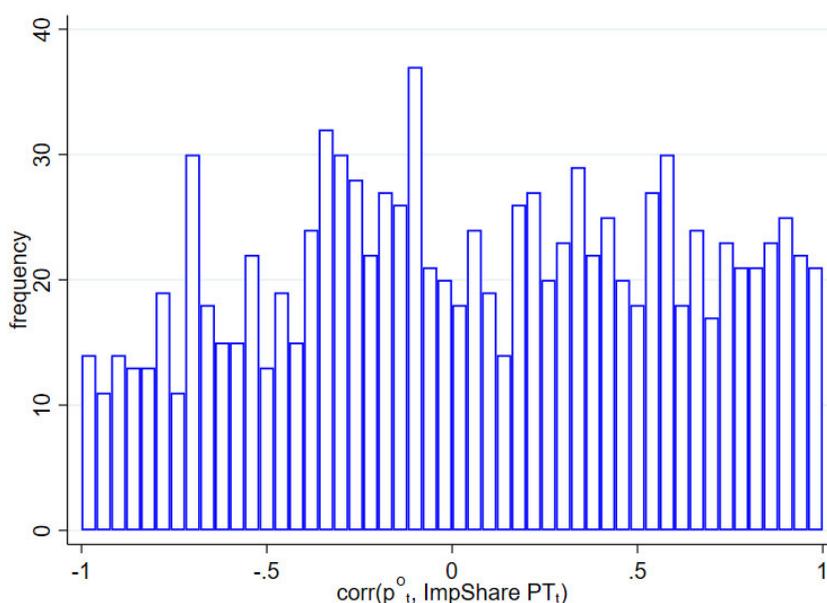
Source: NERA analysis based on data provided for the German market.

As the graph shows, the correlation coefficients tend to be rather evenly distributed: there are products for which originator prices go hand in hand with parallel trade market shares (correlation coefficients close to 1), and there are others for which they move in opposite directions (correlation coefficients close to -1). There are yet others where no clear relationship is visible (correlation coefficients close to 0). While parallel trade must affect all products, only those with a negative correlation will be considered for the quantification, since they are the subset for which the impact can be reasonably isolated from this correlation alone, given that outside and product-specific factors should play a minor role.

As we have stated, having products showing positive correlations between these two variables are an expected result since, as we have stated, parallel trade must always exert competitive pressure, but this is sometimes reflected through a reduction in the rate at which the originators' prices increase. Thus, without parallel trade, price rises would have been even higher.

Besides, for some products, manufacturers would prefer not to lower prices if they are exposed to competition from parallel traders, as price reductions in Germany could lead to price reductions in countries using the German prices as a reference under their ERP systems. Manufacturers, therefore, would rather lose market share to parallel importer in Germany but maintain their price levels in order to keep prices up in other national markets.

Moreover, many of the products exhibiting positive correlations can indeed be reducing their prices but only within a rebate scheme agreed with GKV-SV.[62] Although we have some information as to which products are subject to rebates, the specific terms and conditions of these agreements are confidential and therefore no quantitative analysis could be conducted.

For all these reasons, the competitive pressure from parallel trade is not always visible through the relationship between prices and parallel trade market shares. While this does not mean that such pressure is small or does not exist, with the data at hand, it is more difficult to establish explicitly a counterfactual price in those cases. We did explore if there was any characteristic suitable to be modeled with the dataset that could help isolate the effect of parallel trade for products with a positive correlation. Among these we tried: the price of the product, the size of the market share of the imported products, the fact that products were subject to rebate agreements or to early benefit assessments, etc. However, none of these variables seemed to fulfill their intended purpose.

5.3. Estimate of Indirect Savings

Indirect savings have been estimated by computing the difference between the "counterfactual" price and the true observed prices for each period, multiplied by the sum of volumes sold by originators and parallel traders (i.e. total market demand).

In order to define the originator's price that would have prevailed if parallel imports had not entered the German market (the counterfactual price), we have relied on **the average price prior to entry of parallel imports**. Thus, this approach focuses only on products that, according to the data, experienced entry of parallel imports in the German market within the period analyzed.

Note that this approach is conservative, in the sense that this does not capture savings from potential competition but only from actual competition. As such, the counterfactual price with no parallel trade could even be higher, since, as we have pointed out, parallel traders may exert downward pressure on originators' prices even if they are never present in the market. Moreover, the analysis was first conducted only for those products showing negative correlations (between parallel trade and originators' prices) but subsequently extrapolated for all the products based on their revenues.

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[62]   The individual rebate contracts with the SHI funds.

The fundamental idea is that prices that correspond to zero import shares in the beginning of the sample period reflect originator prices prior to market entry by parallel traders. Hence, the aim is to exploit this change in the market environment by assuming that without entry, there would have been no change in the average price of originators. This rests on the assumption that no parallel trade took place prior to 2011.[63] For that reason, we restrict the analysis to products that experienced at least three consecutive years without competition by parallel traders at the beginning of the sample period (i.e. the years 2011, 2012 and 2013; entry can thus at the earliest take place in 2014). Indirect savings are then calculated for all subsequent years after positive import shares can be observed for the first time. Because only a fraction of the products is subject to market entry, we also provide the results expressed as a percentage of originators' revenues for the products for which savings have been quantified.[64] Such a percentage could, then, be used as an estimation of indirect savings for other products. The assumption behind this is that all other products must have been affected by parallel traders when these entered the market for the first time; before the period for which we have had data.

Our estimation yields indirect savings that amount to **16.7%** of originators' revenues for those products with negative correlations. This can give a better idea of the dimension of the savings in relation to the market. If all products are affected in a similar way, indirect savings would account for approximately **17%** of the originators' market.

5.4.   Summary

Our best estimate (albeit conservative in many aspects) of the indirect saving for the German market yields approximately 17% of the market supplied by originators.

This result, however, is only a lower bound or an underestimation of overall indirect savings since they do not capture indirect savings that accrue due to the threat of potential market entry of parallel imports, as manufacturers might reduce prices or engage in rebate agreements to prevent entry from parallel traders in the first place. Besides, indirect savings could be much larger but captured by the rebates offered by manufactures (and for which no public information exist) and/or hindered by different anticompetitive strategies implemented by manufacturers or pricing decisions influenced by the ERP systems.

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[63]   In the dataset, market shares of parallel traders fluctuate and might as well switch between zero and a positive number throughout the 2011 – 2017 years. It is assumed, that once parallel trade has entered the market (i.e. market share is larger than zero), an originator product is subject to competition by parallel traders regardless of fluctuations in the market share of parallel imports.

[64]   Altogether, there are around 73 products in the data that meet the criterion described above and exhibit market entry.

6.   Indirect Savings in Sweden

6.1.   Regulation and pricing

Most healthcare services in Sweden are publicly funded and cover all legal residents. There also exists a broad range of private insurance companies for patients interested in extended services. Swedish healthcare system also provides essential healthcare to non-residents (i.e. visitors from other EU Member States, asylum seekers, etc.). The purpose behind universal coverage is to provide care to everyone, regardless of income and employment status.[65]

The main source of public funds for health insurance are general taxes levied by county councils and municipalities. Other sources include user fees and national government grants. Public contributions finance approximately 83.5% of total healthcare expenditures. The remaining part is split between voluntary healthcare payments schemes and patient co-payments.[66]

The responsibilities with respect to the organization of the healthcare system in Sweden are divided between national, regional and local authorities. The central government, through the Ministry of Health and Social Affairs, regulates and supervises the system. The healthcare system is mainly steered at the regional level with county councils being responsible to govern financing, organization and provision of healthcare services.[67]

In order to receive market authorisation for the commercialisation of a pharmaceutical product, pharmaceutical companies must apply to either the Swedish Medical Products Agency or the European Medical Agency,[68] who analyse the medicine's quality, safety and efficacy. The agency then classifies the drug as either prescription-only or over-the-counter and decides whether it is substitutable for other already available medicines.[69]

To ensure equal access to effective pharmaceutical therapy, Swedish authorities have established a pharmaceutical benefits scheme. Hence, after receiving authorisation, pharmaceutical companies can apply for inclusion in the reimbursement list. The application must also include a proposed price for the medicine, so that the Dental and Pharmaceutical Benefits Agency, which is the organisation responsible for the pricing and reimbursement decisions, can evaluate all the benefits of the product in question and contrast it against the proposed price. As a result of health technology assessment, the board decides regarding the

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[65]   See OECD/European Observatory on Health Systems and Policies (2017b) pp. 12.

[66]   Based on the Global Health Expenditure Database provided by the World Health Organization, the Swedish government expenditures on healthcare in 2016 accounted for 83.51% of total health expenditures. The rest was covered by household out-of-pocket payments (15.24%) and voluntary healthcare payment schemes (1.25%). Note that pharmaceutical spending is usually not the sole component of total health expenditures.

[67]   See OECD/European Observatory on Health Systems and Policies (2017b), pp. 6.

[68]   Market authorisation through the European Medicines Agency (EMA) grants market access to the entire EU and European Economic Area (EEA) market. This centralized market authorization procedure allows pharmaceutical companies to submit a single marketing-authorisation application. It is compulsory for new active substances in areas such as cancer, HIV, neurodegenerative diseases or auto-immune diseases, and optional for some other diseases.

[69]   See Dental and Pharmaceutical Benefits Agency (2017b), pp. 10-11.

eligibility for reimbursement based on cost-effectiveness, needs and the solidarity principle, as well as the human value principle.[70]

Pharmaceuticals facing competition from more than one manufacturer are subject to the generic substitution rule:[71] pharmacists are obliged to inform patients about available substitutes, and only the cheapest product available is supplied under the Swedish pharmaceutical benefits scheme. The Swedish authorities define substitutability of medicines on the basis of identical active substance, strength and pharmaceutical form.[72]

Every month the Swedish Dental and Pharmaceutical Benefits Agency publishes a list of preferred products with two back-up products for every substitution group. These products are covered by the benefits scheme and have priority when dispensed by pharmacists to patients.[73] Individuals who voluntarily choose other products are obliged to either cover the difference between reimbursement price and retail price of the chosen product or cover the entire costs if the chosen medicine is a different substitute.[74]

The evaluation process can take up to 180 days, during which the medicine is available on the market without reimbursement. Hence, patients voluntarily buying products not included in the benefits scheme must bear the entire costs during this period. This leads to higher out-of-pocket spending or delayed access for some of the patients.[75] The Managed Entry Agreements (MEA) between pharmaceutical companies and county councils have been used as a solution for this delayed in the access to new pharmaceuticals. MEA is a tool that allows to share the risks and uncertainties connected to the introduction of new treatments. The existence of such a type of agreement between the manufacturer and county council may positively affect and accelerate the reimbursement decision.[76]

Although the pharmaceutical companies can initiate a price increase or decrease, the ultimate decision remains in the hands of the authorities. The agency can also review the existing pricing and reimbursement status of medicines in terms of cost-effectiveness. Such review may lead to price reduction or a change in the reimbursement status.[77]

The reimbursement system within the out-patient sector is based on the individual consumption of pharmaceuticals during a time period of 12 months. In general, there is only one discount system, that defines the amount of the patient's co-payments, which can be between 0 and

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[70] See Moïse & Docteur (2007), pp. 15-17.

[71] See Moïse & Docteur (2007), pp. 22.

[72] See Swedish Medical Products Agency (2010).

[73] See Dental and Pharmaceutical Benefits Agency (2017b), pp. 34.

[74] See Dental and Pharmaceutical Benefits Agency (2017b), pp. 46.

[75] For more details about *time to market* problem, see Moïse & Docteur (2007), pp. 19-20; Dental and Pharmaceutical Benefits Agency (2017b), pp. 18 and Panteli (2016), pp. 19-26.

[76] See See Dental and Pharmaceutical Benefits Agency (2017b), pp. 32-34. For a detailed discussion on MEAs in Europe, see Ferrario & Kanavos (2013).

[77] See Dental and Pharmaceutical Benefits Agency (2017b), pp. 31.

100%. However, some patient groups, depending on socio-demographic characteristics, are granted 100% cost coverage, regardless of their individual consumption.[78] Currently a threshold of SEK 2,250 annually is set, which defines the maximum sum that each patient must spend on prescription medicines.[79]

The reimbursement schemes can be divided into two following subgroups:[80]

a) **General Reimbursement**: pharmaceuticals are reimbursed by the healthcare system for the entire approved area of use; and

b) **Restricted Reimbursement**: pharmaceuticals are reimbursed only for a certain are of use, a specific group of patients or under special conditions

In the out-patient sector, only community pharmacies are allowed to sell prescription-only and most over-the-counter pharmaceuticals. A small selection of over-the-counter products can be also purchased at supermarkets or other retailers. The pharmacy retail margin is regulated by the authorities. However, pharmacy mark-up policy concerns only medicines included in the benefits scheme. Pharmacists are thus allowed to freely set up their retail margin for all other products. Until 2009 the pharmacy retail market was entirely owned by the government. However, this situation changed with a new regulation in 2009.[81]

In the in-patient sector, patients are obliged to participate in the costs for the healthcare services (including pharmaceuticals received during hospitalized treatment) in form of direct user charges. Even though the medical appointment fees vary across counties and municipalities, patients' co-payments are capped at SEK 1,100 per year.[82] Since regional authorities organize and decide over the form of the therapies in the in-patient sector, there does not exists a reimbursement list of medicines for in-patient pharmaceuticals. The patient co-payments for the medicines are however covered by the direct user charges already.[83]

The process of procurement of medicines for in-patient use is entirely managed by the county councils. For this purpose, the authorities negotiate directly the price with the manufacturers.[84] If the medicine is available in the out-patient segment, its price setting is used as a reference for hospital use.[85]

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[78]   See Dental and Pharmaceutical Benefits Agency (2017b), pp. 44-45.

[79]   See Dental and Pharmaceutical Benefits Agency (2017a).

[80]   See Dental and Pharmaceutical Benefits Agency (2017b), pp. 42-43.

[81]   See Dental and Pharmaceutical Benefits Agency (2017b), pp. 24-26, 39-41.

[82]   See OECD/European Observatory on Health Systems and Policies (2017b), pp. 6-7.

[83]   See Dental and Pharmaceutical Benefits Agency (2017b), pp. 55.

[84]   See Håkonsen & Sundell (2015), pp. 217-218.

[85]   See Dental and Pharmaceutical Benefits Agency (2017b), pp. 27.

6.1.1.   Parallel Imports

Swedish parallel traders and other pharmaceutical companies can in principle set their own prices. However, for their products to be included in the benefits scheme, the Dental and Pharmaceutical Benefits Agency must approve these prices. This policy is related to a generic substitution law introduced in 2002 that requires pharmacies to dispense the cheapest available products, which includes parallel imports as appropriate substitutes.

For the Dental and Pharmaceutical Benefits Agency to approve a price of a medicine and include the product in the benefits scheme, the requested price cannot exceed the price level of the most expensive item within the substitution group. In practice, this means that parallel imported pharmaceuticals are always priced at the level of originator's prices or lower, as they enter the market after the originator.[86]

Parallel imported medicines as well as generics included in the benefits scheme can profit from such policy, for as long as originators keep their prices at a higher level. In Sweden, market shares for parallel imports reach 13-14% between 2003 and 2016.[87] This is the second highest among European countries, only behind Denmark.

6.2.   Empirical analysis

6.2.1.   Data preparation and description

For the Swedish market, the analysis was performed on a dataset which provides a monthly time series covering a rather short period of time, from July 2015 to June 2018. The raw dataset comprises about 16,300 different medicines, 4,050 of which represent parallel imports.[88]

The data were processed in a similar fashion as the German analysis, so that market shares and average prices could be analysed. Since the data do not identify pre-defined groups of interchangeable products, equivalent product groups were built by combining information on the strength of the product, the strength of the active substance and the package size. Again, we refer to groups of interchangeable products as unique products and the analysis was restricted to the products that did not face generic competition (products still protected by patents). We have identified these products as those exhibiting only one manufacturer throughout the entire sample period. However, we cannot rule out that there might still be generics if the product in that case was supplied only by a single company. After this filtering process, we have obtained 7,200 products fulfilling these criterions.

Subsequently, sales volumes and revenues were aggregated at the product and half-year level. Thus, we have converted the monthly dataset into a half-yearly dataset, which can more appropriately reflect the time sensibility and dynamics of this market (we do not expect originators prices to react instantly to competition from parallel trade). Hence the data spans six time periods, from the second half of the year 2015 to the first half of the year 2018.

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[86]   See Moïse & Docteur (2007), pp. 22.

[87]   Calculations are based on the shares of parallel importers as reported by the European Federation of Pharmaceutical Industries and Associations in the annual "The pharmaceutical Industry in Figures" reports 2005-2018.

[88]   Overall, this corresponds to about 1,500 different level 5 ATC codes.

Afterwards, imported and originator products were matched based on product groups resulting in the end in 1,080 different products.

We computed unit average prices for originator products and imported products as well as the market share of parallel imports by product. We find prices to be dispersed rather widely, from SEK 1 to approximately SEK 142,000. However, there was still a noticeable difference between prices by originators and parallel importers (the former being higher).

The macro figures show that this is a market with a growing size. Both, originators' and parallel importers' revenues have experienced a steady increase. As such, originators' revenues have increased by 19% from about SEK 3,4 billion to more than SEK 4,0 billion in the analysis period. Revenues generated by parallel imports have grown by 21% from SEK 1,200 million to roughly SEK 1,450 million. Overall, the total market share of parallel imports across all products represented in the dataset varies between 14% and 30%.

6.2.2.   Correlation between parallel trade and originators prices

Alike the data for Germany, we have determined the relationship between parallel importers in the market and the observed prices for originator's products by means of their correlation coefficients. The graph below shows the distribution of the correlation coefficients between originators' prices and parallel traders' market shares of each product.

Figure 6.1.   Frequency Distribution of Correlation Coefficients (Sweden)
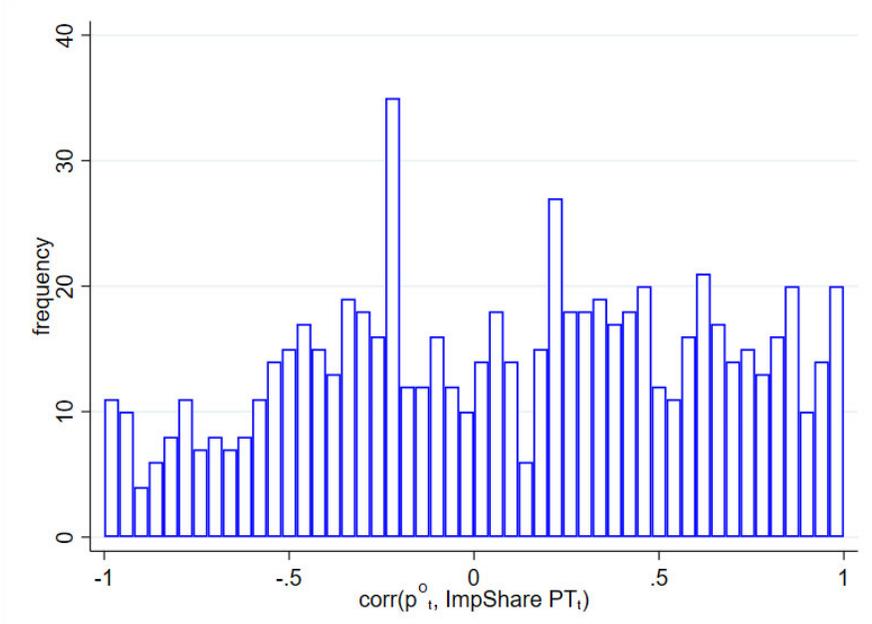
Source: NERA analysis based on data provided for the Swedish market.

The results are consistent with those for Germany: correlations between originator prices and the market shares of parallel traders tend to be evenly distributed. Thus, there are products for which an increase in the market share of parallel traders is associated with a reduction in prices but other for which the opposite effect is observed.

Thus, alike Germany, a negative correlation can only be observed for a subset of products, and, thus, the estimation is methodologically restricted to this subset of data. Nevertheless, as usual, we expect parallel trade still to exert a pro-competitive effect across all products.

As we have stated above, the reasons why the competitive pressure from parallel trade are not clearly visible for all products by means of a negative correlation between prices and parallel trade market share are explained by many factors. For instance, because rather than reducing prices parallel trade oftentimes prevents prices increases, or because manufactures might prefer to keep prices up in Sweden in order to avoid further price reductions in markets using Sweden as a reference within their ERP system.

Regardless of these considerations, it is also true that the observation period length for the Swedish data is shorter and therefore it is more difficult to capture dynamic effects.

6.3.   Estimate of Indirect Savings

Indirect savings have been estimated for the subset of products featuring a negative correlation. Again, the computation of indirect savings requires the estimation of a "counterfactual" price, i.e. the price that would have been observed in a scenario without parallel trade. Indirect savings can then be calculated by multiplying the price differential (counterfactual price minus real observed price) by the total volume sold in the market.

To determine the counterfactual price for the Swedish pharmaceutical market, we draw on the same approach as in our analysis for Germany: **the average price prior entry of parallel imports**.

In order to apply this approach, again, market entry must be defined. Besides, the analysis should be restricted to products that were not subject to parallel trade for a sufficiently long period of time at the beginning of the sample period. However, in this case this can be problematic due to the limitations of the Swedish data that only covers a few years. For this reason, the analysis is restricted to products that exhibit zero market share of imports in their first (six-month) period only.

This procedure rests on the assumption that the respective products were not subject to parallel trade before the sample period, which may be a strong assumption. Therefore, results must be interpreted with care. Nevertheless, it is worth noting that if a product was subject to parallel trade shortly before the second half of 2015 and parallel trade exerted a negative effect on originators' prices, this procedure would be conservative (it would suggest lower savings).

As only a certain fraction of products with negative correlation qualifies for the approach, an extrapolation to the full sample was made.[89] Again, the extrapolation is based on the share of products used in the analysis in terms of market value. Applying this approach results in indirect savings that represent **12.3%** of the market revenue for originator products.

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[89]   Around 110 products were used in the analysis as they featured a negative correlation between originators' prices and parallel trade as well as zero imports in the initial sample period.

6.4.   Summary

Our best estimate -albeit conservative in many aspects- of the indirect saving for the Swedish dataset yields approximately 12% of the market supplied by originators.

Alike Germany, this methodology does not capture indirect savings due to potential competition or due to a reduction in the rate at which originator's prices increase. Besides, manufactures in Sweden may also have incentives to keep prices up despite the competitive pressure from parallel trade, because of the ERP system.

7.   Conclusion

Even though the methodology pursued in this report allows for the explicit estimation of indirect savings for only a subset of products we can extrapolate the results for the full market. Moreover, our methodology very likely underestimates overall savings.

Nonetheless, we have found important savings in both markets, consistent with the competitive pressure that economic theory credits to parallel trade. **Our approach yields indirect savings in the pharmacy channel that represents 16.7 and 12.3% of the originator revenues for Germany and Sweden, respectively.**

This does not in any way suggest that the competitive pressure exerted by parallel trade is limited to only a subset of products; rather, this is the result of a methodological restriction which prevents such explicit calculations for products where external and product-specific factors play a role in shaping price trends.

It is important, as well, to bear in mind that all these results can be reasonably interpreted as only a lower bound of overall indirect savings. This is because the methodology pursued is very conservative and considers only savings that can be inferred from a visible relationship between parallel trade and product prices. Among the savings that are not considered in the estimation and could add up to a higher overall figure and percentage are indirect savings due to the threat of market entry of parallel imports (potential competition), higher savings that could be computed with higher counterfactual prices from larger datasets, and savings by means of rebates or discounts whose information is not publicly available.

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