

The Parallel Distribution Industry

A closer look at savings

*A report prepared by the European Association of
Euro-Pharmaceutical Companies (EAEP C)*

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Preface

Parallel distribution in medicines has existed in Europe for over thirty years, bringing competition to an otherwise closed pharmaceutical market and providing improved and cheaper access to medicines for European patients. While the practice has been recognised as 100% legal since its inception, controversy on its economic impact has surrounded its development for several years. In fact, the parallel import industry is one which actively plays a positive role in keeping drug prices low, helping to assist EU member states with their healthcare budgets and offering patients access to cheaper medicines.

Parallel distribution offers a truly European solution to member states' healthcare funding deficits. As the expression of free trade, it avoids or minimises the implementation of other, more interventionist or market-distorting cost-containment measures, and it helps to mitigate the impact of the current economic downturn on European citizens, allowing them to continue to access modern medicines at affordable costs, even when their own budgets are being squeezed.

With the present study we would like to offer an overview of the monetary savings generated by the parallel import (PI) industry across the European Union, with a focus on newly developing PI markets. Commissioned by the European Association of Euro Pharmaceutical Companies (EAEPCC), the trade body representing the PI industry, the study draws on information provided by EAEPCC members in six markets: France, Italy, Poland, The Netherlands, Latvia and Ireland.

The study aims to provide an insight into the pivotal role played by our industry in offering affordable drugs across the EU. We hope you will find it of interest and are looking forward to a constructive discussion on the role the parallel distribution industry can play to help Europe's economy thrive.



Andreas Mohringer
EAEPCC President

Table of abbreviations

EAEPC	European Association of Euro Pharmaceutical Companies
ECB	European Central Bank
EFPIA	European Federation of Pharmaceutical Industries & Associations
EU	European Union
GERS	Groupement pour l'élaboration et la réalisation de Statistiques
IMS	Intercontinental Marketing Services
LSE	London School of Economics
PD	Parallel Distribution
PI	Parallel Import

Executive summary

Parallel distribution of pharmaceuticals is an important part of the healthcare market in Europe. It has existed since the 1970s, but has increased significantly in size and importance with the evolution of the single market and, together with the enlargement of the EU, has extended to new markets. That PI generates savings in Europe is not disputed any longer. The question is more how much savings it generates, to whom these savings accrue and whether the patient, and the final payer - in most cases the health insurance system - draw a significant benefit from the commercial practice of parallel distribution. These are the questions we have tried to answer by analysing the savings in the markets described below.

The six reference markets - France, Italy, Poland, The Netherlands, Ireland & Latvia - are all markets where PI has taken on a greater significance in recent years. These markets vary greatly in size from The Netherlands, where the PI market was valued at €850m in 2011¹, to France where the market was valued at €12.7m² in the same year. The report's main findings are as follows:

- As a preliminary remark, it should be noted that, due to the relative novelty of PI in some of the markets covered, and sparseness of available data, it is often hard to demonstrate the exact value of savings.
- Best indications show that in Poland direct savings reached the equivalent of €6m in 2009 and a total of €17m in the four year period 2005-2009, in France total direct savings in 2011 amounted to €638,000, while in Ireland direct savings totalled €4.18m in 2011. Separately, best estimates for 2011 indicate that in The Netherlands direct savings reached €12.75m.
- In all markets, PI 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 €22m in 2009 for Poland and €39m in 2011 for France. Price decreases on originator drugs through PI have also been noteworthy in Ireland, where in 2010 Pfizer decreased the price of some of its products by up to 47% of the original prices, due to competition from cheaper PI.
- Agreements between importer associations and the Irish and French governments have led to lower reimbursement rates for PI products, which, as a knock-on effect, have increased savings for health systems in both countries. For example in France, PI products are reimbursed at a rate 5% lower than the reimbursement rate of the equivalent originator products, whereas in Ireland, there is a practice in place whereby parallel importers

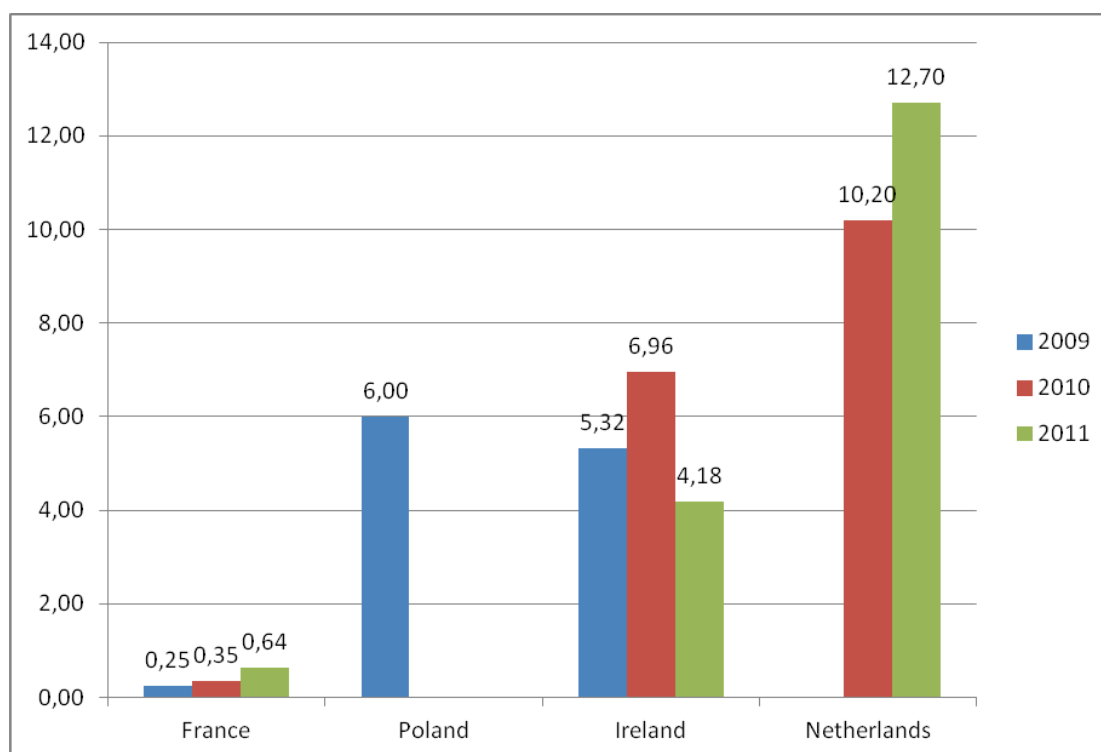
¹ According to IMS data from 2011

² According to GERS data from 2011

request a reimbursement price of 3% or more below the originator's price of the medicine. In order not to deter pharmacists from dispensing PI products, in both countries, PI companies offer a higher discount to pharmacies purchasing PI products.

It should be noted that the current level of direct savings in the markets covered is based on the number of PI product authorisations per country. An increase in the number of new PI authorisations issued by a national regulator is a determining factor in the calculation of savings generation; it will also lead to more significant sales volumes, which in turn may lead to market pressures on originators to reduce their prices and make headroom for additional indirect savings.

Table 1: A comparison of direct savings in 4 PI markets for 2009, 2010 and 2011



All figures are in €m and for Poland ECB historical exchange rates were used to calculate the values. Direct savings data for Poland was not available for 2010 and 2011 or for the Netherlands in 2009.

Introduction

The principle of free movement of goods, services and people has been one of the building blocks of the European Union. Over the years, this principle has inspired the creativity of entrepreneurs who have seized the wealth of opportunities generated by the creation of the internal market. The development of the practice of parallel distribution is one such example. For those unfamiliar with the term, parallel distribution of medicines is the legal activity of authorised wholesalers who buy products in one EU country, to sell them in another, in parallel and thus in competition with the distribution systems set up by manufacturers, generating savings for patients, governments and health insurers alike.

The practice is 100% legal and encouraged by many governments and regulators in order to foster competition, and is the logical consequence of the differentiation of prices between EU member states. It also represents a significant component of the European medicinal supply chain. According to recent IMS data, approximately 5% of prescription drugs in Europe are currently parallel imported, with a volume equating to roughly €5.2 billion of the total EU pharmaceutical market per annum.

As such, parallel distribution is an important practice in Europe, one that is surrounded by much economic interest, as well as controversy.

This study seeks to bring some clarity into the debate and, in particular, demonstrate the benefits, in terms of savings, that the sector brings to patients and governments, particularly in newly developing PI markets. Indeed, more recently, several EEA countries have experienced an evolution in their pharmaceutical PI market, which has now become a significant player in the overall pharmaceutical distribution chain. This includes "old" member states such as Ireland, Italy, The Netherlands and France, but also "new" member states like Poland and Latvia. In this study we attempt to provide significant data on savings from these markets, with a view to capturing the full picture of economic benefits derived to patients and payers across the EEA area.

The study builds on data provided by the members of the EAEPIC, the trade body representing Europe's licensed parallel distribution industry; and focuses on data from the six newly developing PI markets mentioned above, covering the period 2009-2011, except for Poland where the data provided is from the years 2005-2009, and Latvia, where data was only available up to 2010. In all cases the data is broken down into direct and indirect savings, following a methodology developed by Professor Kjeld M. Pedersen of the University of Southern Denmark in an initial study published in June 2006³.

³*The Economic Impact of Parallel Import of pharmaceuticals*, Ulrika Enemark, Kjeld Pedersen & Jan Sørensen, University of Southern Denmark, 2006.
http://static.sdu.dk/mediafiles//Files/Om_SDUCentre/CAST/PDF_filer/parallel_import_rapport_13_06_1430_opdateret_final2.pdf

What is parallel distribution?

Parallel distribution occurs when products which are purchased at a lower price in one country are transported for resale to other countries where they can be sold at higher domestic prices. This process puts the parallel distributed products in competition with the same “originator” product which is provided, in the destination market, by the original trademark owner, i.e. the manufacturer or the local licensee of the product. Parallel distribution of medicines is essentially a business built on the medicines’ price differential across the EU member states and is 100% legal.

Why is parallel distribution happening?

The basic underlying driver of parallel distribution is the variation in the manufacturers’ price for otherwise identical pharmaceutical products across markets. Such price variations are, among other things, the results of different national regulatory environments, in particular price negotiations and regulation; a degree of monopolistic power on the supply side; price discrimination; and price-setting responses to exchange rate variations.

How does parallel distribution lead to savings?

Economic theory shows that the short-term effects of allowing parallel distribution of drugs stimulates direct savings to purchasers of pharmaceuticals in importing countries as PI are sold at a lower price than the originator price.

Indirect savings are more difficult to measure as it requires assumptions about how prices would have developed in the absence of PI and about the causal link between PI and changes in the price of the direct import. Savings may arise either because competition results in price decreases (or reduces the price increases below the level expected without competition) or because the potential competition leads to limit pricing (where the manufacturer chooses to reduce the domestic price to a level at which it is less profitable for parallel importers to enter the market).

Methodology

In the empirical literature a debate exists as to whether PI do in fact lead to savings. Two studies on the issue dominated the debate in the early 2000s, the York study⁴, which concluded that parallel distribution did contribute to savings (over €600 million in five countries in 2001), and the LSE study⁵, which argued that savings generated by parallel distribution were negligible⁶. A third study on the impact of PI on savings by Pedersen and Enemark in 2006⁷ sought to address these differences by

⁴ *Benefits to Payers and Patients from parallel trade*, West, Peter & Mahon, James, York Health Economics Consortium, 2003

<http://archives.who.int/prioritymeds/report/append/8210ParallelTradeReport.pdf>

⁵ The Economic Impact of Pharmaceutical Parallel Trade in European Union member states: A stakeholder analysis, Panavos Kanavos et al, London School of Economics, 2004
<http://archives.who.int/prioritymeds/report/append/829Paper.pdf>

⁶ The York study was commissioned by the EAEPIC whilst the LSE study was commissioned by Johnson & Johnson.

⁷ Pedersen and Enemark’s study was commissioned by the EAEPIC

assessing the two methodologies, and it concluded that the approach taken in the York study was the more accurate of the two. The main reason lay in the fact that the York study was based on fuller market data of parallel imported products while the LSE study evaluated only a selection of products which, in part, were not even significantly parallel distributed and hence did not generate measurable savings.⁸ Whilst the York study focused on the top-selling products and additionally a random sample of 150 products in the countries it analysed, the LSE study only focused on a selection of six product categories that covered 21% of the brand market and used the same products in all its selected countries, even though some of these products were not subject to PI. Therefore, due to the more encompassing nature of the York study, the present study adopts the same methodology as the one used for the 2006 Pedersen study.

Calculations for savings in the six countries described are broken down into “direct” and “indirect” savings. Direct savings are relatively straightforward to measure as they result directly from the difference in medicine prices between the manufacturer’s originator product and the parallel imported product, multiplied with the number of PI packages dispensed in a given period. This straightforward procedure is based on an implicit assumption that there is no quantity effect of the reduction in prices, i.e. the consumption of a drug does not increase as cheaper PI products become available. This seems to be a reasonable assumption as price is not likely to be a main determinant for either prescription or consumption. Prescribers are not involved in the selling of drugs and consumers of prescription drugs at most pay a modest co-payment (most of the payment is through a third party). Any bias that would arise from this omission would tend to be an overestimation of direct savings.

Indirect savings – which result in price concessions by originators – are calculated either as the margin by which a manufacturer decreases the price of a drug, or by the declining margins by which a manufacturer increases the price of a drug – as is often the case with over-the-counter medicines - due to sustained competition by a cheaper PI product, multiplied by the volume of originator medicines sold in the reference period. These savings are expressed as the cover price for all medicines where there is a price drop included in this drug category, due to competition from the PI product. It is not known, however, how prices would have developed in the absence of PI.

Furthermore, in the case of Poland, the results are based on a study undertaken for the Polish market in 2010 by Deloitte⁹ and the data was audited externally. For France, the data provided are certified GERS¹⁰ statistics.

⁸ *The Economic Impact of Parallel Import of pharmaceuticals*, Pedersen et al, 2006.

⁹ SIRPL commissioned report on the Impact of parallel import on the competitiveness of the pharmaceutical market in Poland, [Deloitte](http://www.importrownolegly.pl/files/upload/SIRPL_Deloitte%20report_10V2010.pdf), 10 May 2010
http://www.importrownolegly.pl/files/upload/SIRPL_Deloitte%20report_10V2010.pdf

¹⁰ Groupement pour l’élaboration et la réalisation de Statistiques, (GERS). It is an economic and data analysis group set up by the French pharmaceutical industry in 1974 to monitor medicine sales:
http://www.gie-gers.fr/groupement/qui_sommes_nous.php3

In order to demonstrate savings in those markets where the € is not the local currency, all currency conversions have been based on current or historical current exchange rates through the European Central Bank's currency exchange database¹¹.

¹¹ <http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html>

Country-by-country analysis

1. France

Since January 2004, PI has been legally promoted in France through the *Décret n° 2004-83*.¹²

Total PI market sales in France were valued at €4,827,260 in 2009, €6,765,592 in 2010 and €12,763,881 in 2011¹³, thus registering a 40% increase from 2009 to 2010 and 73% from 2010 to 2011. Separately, in 2011, the market of reimbursed products in pharmacies (excluding hospitals) amounted to €19.516m, a 0.3% increase on the previous year. Currently, PI has a market share of 0.06% of the French pharmaceutical market of reimbursed products.

The current level of direct savings in France is based on 69 PI product authorisations. At the time of editing this report, around 50 additional requests for PI authorisations were pending, offering potential for additional savings to be generated.

Direct and indirect savings

In France, the general conditions of the country's reimbursement system are established by law and implemented principally at national level by governmental bodies. When a marketing authorisation is granted either by the EMEA or the French Medicines Agency (ANSM), a company then has to apply for reimbursement to obtain funding for its products by the mandatory health insurance. The Economic Committee on Health Care Products (CEPS) fixes the medicine price after negotiation with the medicine company. In the spring of 2011, it reached an agreement with parallel importers so as to ensure that PI versions of medicines are priced (and as a consequence reimbursed) at a rate 5% lower than the price/reimbursement rate of the equivalent originator products.

Taking this 5% reimbursement differential into consideration, **direct savings** generated by PI in France reached over €356,000 in 2010, and €638,000 in 2011¹⁴, marking a year-on-year increase across the two years of 79% in savings generated for the French social security services.

Looking ahead, it has been calculated that, if 100 import licenses for medicinal products were licensed in France, and assuming that PI could achieve a 10% market share of the products on which it competes with originators, total savings generated could amount to €17m. Indeed, at the time of publication, an additional 50 requests for PI authorisations had been introduced, offering potential for further savings in France.

¹² The décret can be found here: <http://admi.net/jo/20040127/SANP0324239D.html>

¹³ According to GERS data

¹⁴ According to latest data from GERS

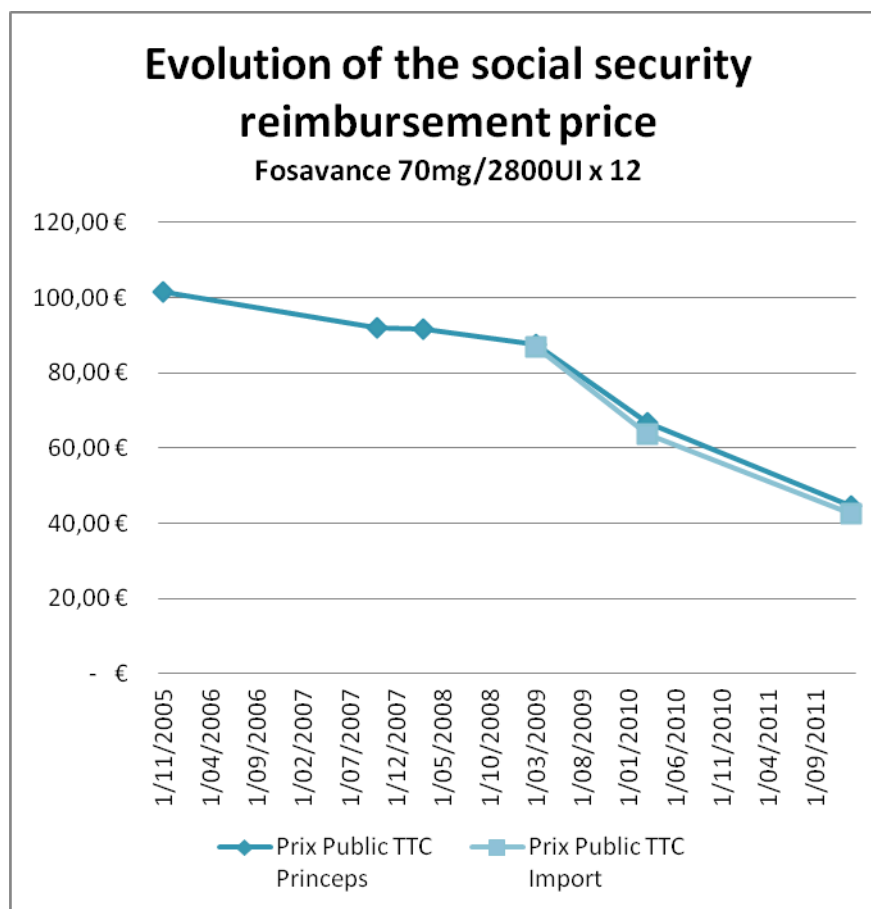
Indirect savings, based on IMS data for 2009, note that downward pressure by PI products on originator medicines generated savings for the French social security services of €36m in that year alone, taken from the examples of four imported drugs on the French market, where there was no equivalent generic competitor.

A good example of indirect savings generated through downward pressure from PI competition is given by the evolution in price for Fosavance (a medicine that helps prevent osteoporosis).

The table below shows the price evolution of the originator version of Fosavance from November 2005 to January 2012. This evolution demonstrates a steep drop in price by the originator product from the date the PI competitor product entered the market in March 2009 at roughly €87 per pack, down to roughly €44.48 per pack in January 2012.

Interestingly, at this price level PI is no longer viable for the French market, so the parallel imported drug has been pulled out of the market – although the French social security system has reaped huge benefits from the competition between the originator and PI drug.

Table 3 – Reimbursement price evolution in France of the Fosavance drug



2. Italy

In Italy, PI of pharmaceutical goods has been legally allowed since 1997, with the first imports commencing in 2001¹⁵. Since then, the Italian national drug regulator, AIFA, has issued approximately 800 PI marketing authorisations/licenses, out of which roughly 270 licenses are currently active, according to IMS data.

In its recommendation to the Italian Government in 2007, the Italian National Antitrust Agency noted that PI was the only way for intra-brand competition and recommended that the Italian Government establish a legal framework for the pricing of parallel imported medicines, incentivising PI and offering savings to the Italian reimbursement system (Antitrust AS 421 dated 25 October 2007)¹⁶.

According to the latest IMS data for 2012, Italian pharmacy sales of PI products are currently valued at around €42m, representing an increase from 2011 and 2010, when PI sales were valued at roughly €37m and €33m, respectively. Whilst PI is still a very small part of the Italian medicines supply, representing 0.36% of the total pharmaceutical market, it is nevertheless a growing market, with 55% of pharmacies in Italy currently dispensing PI products¹⁷.

Direct & Indirect savings

Elaborating on 2011 IMS sales data, the Italian PI industry has demonstrated to the Italian Ministry of Health that through a mandatory discount (or clawback) of 3% on all reimbursed medicines sold by PI companies, the Italian Government could have generated **direct savings** of up to €3.6m in 2011. This simulation was based on the number of PI licenses active as of February 2011.

As regards **indirect savings**, PI has been shown to have had a “stabilising effect” on the price of originator medicines on the Italian market. A good example of this is the case of Daflon, a compound produced by French manufacturer Servier, which is used for mitigating the effects of varicose veins. When the PI version of the product was introduced onto the Italian market in late 2000, the price of Daflon stood at €12.86 per pack. Although by February 2007, the price of the originator had increased to €14.28, a level at which it has subsequently remained, the price increases of the originator decreased incrementally, due to the impact of the presence of cheaper PI

¹⁵ It was not until 2001 that the first import authorisation was awarded by the Italian authorities, when the initial business rationale for imports became evident.

¹⁶ “At present, the law that regulates the authorizations for parallel imported pharmaceutical products does not contain... a specific facility in regard to pricing of parallel imported pharmaceuticals which would, on one side provide an incentive to the importers and, on the other side guarantee that the higher trading margin obtained through the practice of parallel trade be in part converted into gains for the SSN (social security). Failing clear rules on pricing of parallel imports, there is a substantial absence of ethical drugs imported from countries where prices (of these drugs) are lower, leading to a lost opportunity for competition and reducing expenditures of the national social security”.

¹⁷ According to figures shared by the AIP, the Italian association of parallel importers.

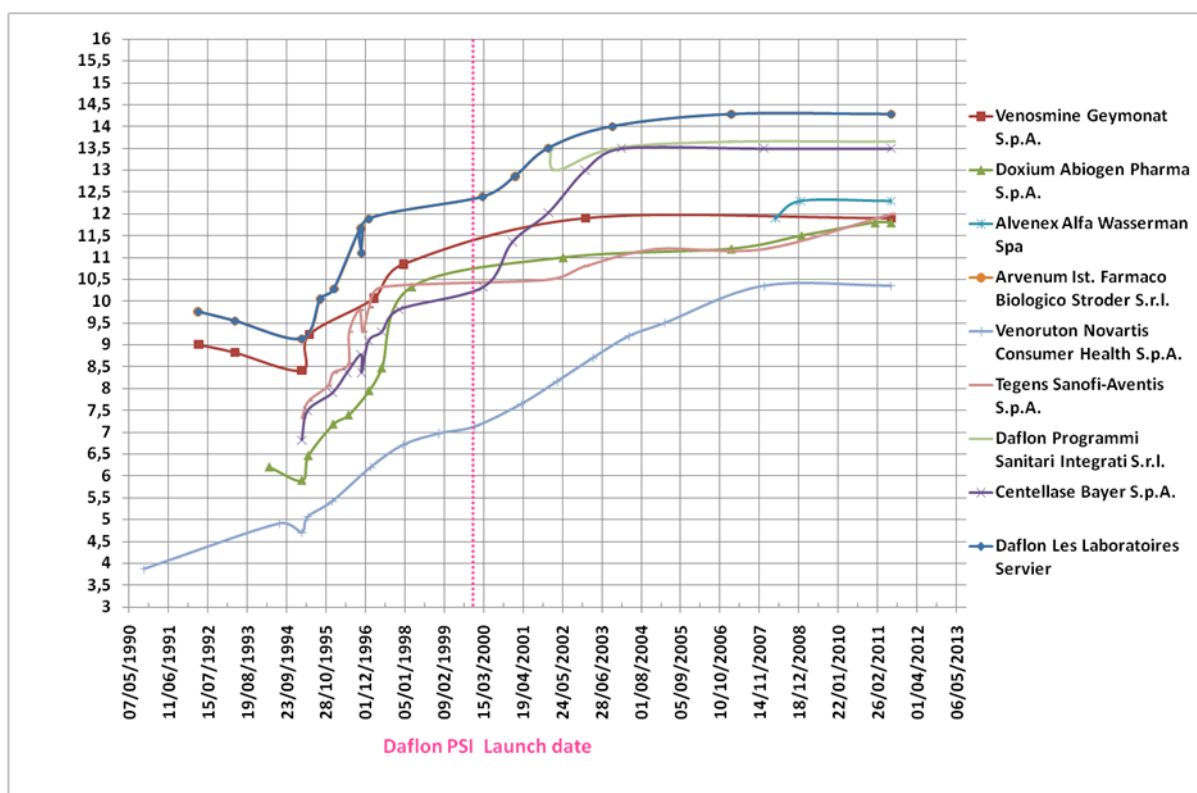
alternatives on the market. Since 2007, there have been no further price increases and the price of the originator product has flattened out.

Table 4 – prices increases of Daflon in Italy in the period 2001-2007.

Date	Daflon Price per pack of 30x 500 mg tablets	Price increase	% increase
29/01/2001	€ 12.86	n.a	n.a
2/01/2002	€ 13.50	66 cents	4.97%
13/10/2003	€ 14.00	50 cents	3.70%
1/02/2007	€ 14.28	28 cents	2.00%

This “stabilising effect” is not only visible in the case of Daflon. The table below shows the impact of the introduction of the PI version of the product in 2000 on prices of originator medicines, fully demonstrating the “stabilising effect” which the introduction of the PI version of the medicines has had on originator prices on the Italian market. As can be seen in all cases, Daflon included, although originator prices initially continued to rise, prices eventually flatten out, with no increase in prices in the period 2007-2011 for any of the products covered.

Table 5 – The impact of a PI product on price increases on the Italian market.



3. Poland

In Poland, parallel distribution has been part of the pharmaceutical landscape since November 2005. The Polish pharmaceutical market is the largest in Eastern Europe with sales generating over 25% of the region's turnover. PI of drugs dispensed in Poland accounts for 1.05% of overall market value and it grew hugely from 2005 to reach 209.5m PLN (€51m) in 2010¹⁸. The growth was fuelled by the rapid increase of drugs registered for parallel distribution – only 165 in 2008, which amounted to 350 authorised products in total. Additionally, the price of PI drugs is usually 10-60% cheaper than the original versions of the product.

In the period November 2005 to year end 2009, the Polish PI industry generated overall sales of 14m packs¹⁹, representing 1% of all sales on the Polish pharmaceutical market.

Direct & Indirect savings

In the period 2005-2009 total direct savings for each of the five years amounted to just over €75m in savings for Polish patients, hospitals and the country's national health fund - with the highest savings being made to the benefit of patients – almost 100% of total savings in the five year period covered. Over this five year period, savings increased year-on-year from just under €285 000 in 2005 to almost €28m in 2009 alone, demonstrating the growth of the industry in the Polish market.²⁰

Hospitals and the Polish national health fund are also making savings through PI products as demonstrated by the increase in the period 2005 to 2009²¹. This is due to the fact that most PI products in Poland are non-reimbursed medicines, where patients pay the full price and directly reap the full benefits of cheaper PIs.

However in the period 2005-2009, the largest share of savings was made in the form of **indirect savings**, which have steadily increased throughout the period covered from just under 1m PLN (€238,000) in 2005 to just under 95m PLN (€22m) in 2009. Polish patients also benefited from **direct savings** throughout the period (cheaper prices for equivalent medicines) and although these savings have been lower than indirect savings, in the three year period from 2005 to 2008, these savings increased from just over 18PLN (€45,000) in 2005 to just over 30m PLN (€6m) in 2008.

¹⁸ According to figures shared by the Polish member of the association

¹⁹ SIRPL commissioned report on the Impact of parallel import on the competitiveness of the pharmaceutical market in Poland, Deloitte, 10 May 2010
http://www.importrownolegly.pl/files/upload/SIRPL_Deloitte%20report_10V2010.pdf

²⁰ Ibid

²¹ Ibid

Table 6 – Total savings generated by PI in the years 2005-2009.

Savings/year	2005	2006	2007	2008	2009	Total
Total savings	1,136,954	25,332,500	50,475,897	96,885,054	120,215,485	294,045,890
Patient savings	1,136,954	25,332,500	50,475,897	96,396,553	119,173,840	292,488,742
Hospital savings	0	0	0	401,491	695,395	1,096,885
National Health Fund savings	0	0	0	114,011	346,251	460,262

(all prices in PLN, from Deloitte study)²²

Table 7 –direct and indirect savings in Poland in the years 2005-2009.

(all prices in PLN, from Deloitte study)²³

Savings/year	2005	2006	2007	2008	2009	Total
Total savings	1,136,954	25,332,500	50,475,897	96,885,054	120,215,485	294,045,890
Direct savings	185,548	2,712,648	14,350,729	29,407,342	26,292,862	72,949,129
Indirect savings	951,406	22,619,852	36,125,168	67,477,711	93,922,623	221,096,760

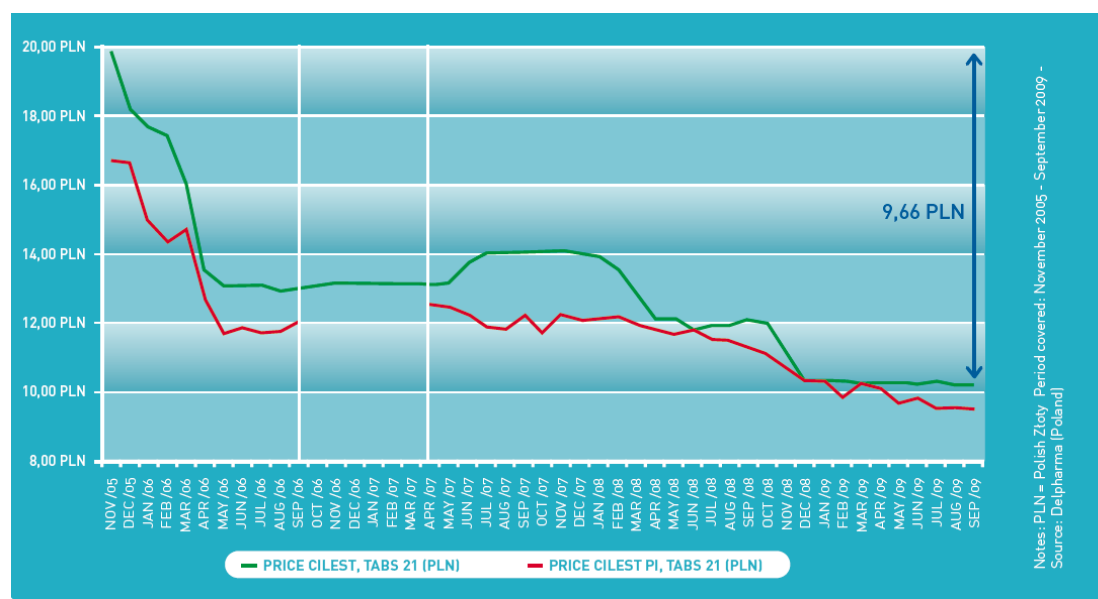
As regards indirect savings, one of the best examples of the impact of PI on originator medicine prices in recent years is the one of contraceptive pill Cilest. In November 2005, when the PI version of the product entered the market, the originator drug was being sold at 20PLN (€5) per pack of 21 tablets. Over the course of a four year period until September 2009, downward pressure exerted by the cheaper PI equivalent of the drug led to a drop in the price of the originator version (as well as the PI equivalent) of the medicine to a price of just over 10PLN (€2.3) per pack, which marked a total decrease over the four year period of over 50% of the original mark-up.²⁴

²² Prices are expressed in PLN; exchange rates calculated using European Central Bank historical rates.

²³ Prices are expressed in PLN .

²⁴ EAEPIC brochure, Parallel distribution, making modern medicines more affordable for European citizens, p.7 [EAEPIC](#), 2010

Table 8 – The impact of competition by PI product on contraceptive originator price in Poland



4. The Netherlands

PI of medicines has existed in The Netherlands since the 1970s and it is the country with the longest history of PI in Europe²⁵. The country has also traditionally been the market with the largest share of PI products sold (out of all drugs sold domestically) within the EU. Latest figures from 2011 put the share of PI in the Netherlands at 17% of the Dutch market for pharmaceuticals²⁶. Separately, according to IMS data from 2010, the Dutch parallel distribution industry accounted for 12% of the entire European PI market share, with the total valuation of the PI market in The Netherlands calculated at being worth €680m in 2010 and then up to €850m in 2011.

PI in The Netherlands is monitored by the Dutch Medicines Evaluation Board, the MEB, and are regulated by article 48GW of the Dutch Pharmaceuticals Registration decree.

All prescription-only medicines sold through pharmacies are subject to the Medicinal Product Prices Act - the Wet Geneesmiddelen Prijzen (WGP) system – with prices set at a maximum level determined twice a year. The maximum retail price of both generic and branded medicines is set by the Ministry of Health, Welfare and Sport and based on the average price of comparable medicinal products in four reference countries.

²⁵ *Benefits to Payers and Patients from parallel trade* West et al, 2003

²⁶ According to data provided by the Dutch member of the EAEP

Direct and Indirect savings

PI products are mostly sold to the public just below the price charged by the manufacturer, offering a savings margin of 1 - 2%, even though there is no law in place which states that PI products should be offered at a cheaper rate than originators' medicines. Taking the above €850m as a reference point, the latest figures on savings in The Netherlands show that total savings generated through PI in 2011 would have amounted to have been in the region of €12.75m.

Imports have not only made cheaper medicines available for Dutch pharmacies, hospitals and patients but have also exerted downward pressure on originator products on the market.

Separately, Dutch re-imburement laws in 2010/11, which have seen generic prices decrease, have led Dutch pharmacists to turn to PI sales in order to increase their own margins. Without revenue generated from purchasing and dispensing cheaper PI, Dutch pharmacies would not economically be in a position to sustain the government policy of dispensing low price and low margin generics as they currently are obliged to.

5. Ireland

In Ireland, PI has existed since 1986 and the current regulatory framework is set by the Medicinal Products Regulations of 2007, with PI licenses being granted by the Irish Medical Board²⁷. In 2010, according to IMS figures, the full market for prescription (RX) and over-the-counter (OTC) drugs in Ireland was valued at €1.737bn, with PI estimated as accounting for 13.36% of this figure, or €232m. In 2011 the total market for RX and OTC drugs was estimated as being worth €1.654bn, whilst the PI share of the market was valued at €139m or 8.4% of the total market share.

In Ireland, there is a practice in place whereby parallel importers request a re-imburement price of 3% or more below the originator's price of the medicine. This is a 'goodwill' offer between the government and parallel importers that was not imposed through legislation. In the case where a patient pays for a medicine privately, then the price he/she pays is 3% below that of the original product. Likewise, if the medicines are reimbursed through a government scheme, then there is a 3% saving made by the government on the PI product sold, in comparison with the originator's product. In addition to this 3% margin, parallel importers offer additional discounts to pharmacies. The economic rationale behind this is that pharmacies should not be deterred from dispensing cheaper PI products and this extra discount helps their overall economic situation, with many Irish pharmacies currently affected by the financial crisis.

²⁷ http://www.imb.ie/images/uploaded/documents/AUTG0006_Guide_to_Parallel_Imports_Human_Medicines_v7.pdf

Additionally, pharmacies get a bigger discount on PI products than they do on originator's medicines.

Direct & Indirect savings

In 2010, it was estimated that PI contributed to **direct savings** of €6.96m, whilst in 2011, these were calculated as having reached €4.18m²⁸.

Looking closer at **indirect savings** generated by PI, a good example is from January 2010, when the Irish Government forced pharmaceutical companies to reduce their prices by an average of 10%. Faced with this measure, most manufacturers decided to target products and modulate prices that were in competition from the generics and the PI industry. In the case of Pfizer, the company decreased the price of its Zoton drug (Lansoprazol, used for decreasing acid build-up in the stomach) by 40%, while this particular drug had a PI market penetration of 61%. Pfizer also reduced the prices of Lipitors by up to 47% of the original price, with 47% of the Irish Lipitor market being covered at the time by PI. By making these reductions, it is estimated that the savings on all Pfizer products for the Irish government worked out at almost 16% of pre-reduction costs.

6. Latvia

PI has existed in Latvia since 2006 with authorisations for PI issued by the State Agency for Medicines (SAM). The latest SAM figures from 2011 show that the number of authorisations for distribution of PI in Latvia has increased from 5 in 2006 to 93 in 2010, albeit with a slight dip in 2008 (see table below)²⁹.

Table 9 – PI authorisations in Latvia 2006-2010

Year	2006	2007	2008	2009	2010
PI authorisations	5	29	19	44	93

The Latvian government is actively supporting PI as a means to impact on overall pharmaceutical pricing. The law on reimbursement sets out that PI reimbursed products must be offered to patients at pharmacy level with a price difference of 10% of the originator retail price. This price advantage also translates into savings for the health (insurance) system in that - depending on the reimbursement rate - the reimbursement is calculated at the lower dispensing price (direct savings).

²⁸ According to figures shared by the Irish member of the EAEPC

²⁹ http://www.vza.gov.lv/doc_upl/gada-parskats-2010-en.pdf Annual Report of State Agency of Medicines, p.13, 2010

Direct and Indirect savings

PI sales since 2006 have had a modest start. One EAEPC member (holding 81 number of product authorisations) reported in 2010 a PI turnover of approximately €1.7m, thus generating savings of roughly €260.000³⁰; extrapolating this to the total 93 authorisations the overall savings could be 2.000 Lats (equivalent to €2.850) on each product to the wider Latvian economy and this includes direct savings for pharmacies, hospitals and patients.

PI have been acknowledged as providing a cheaper alternative to originator medicines as was demonstrated by a pharmaceutical sector enquiry in 2011 by the Latvian Competition Council, aimed at establishing means for reducing pharmaceutical prices. The Council recommended that restrictions to market entry for PI (and generics) be removed as such restrictions served to benefit producers of more expensive drugs³¹.

Pedersen study: updated figures

7. Denmark

Total savings generated through parallel imports have risen steeply, with total savings in 2011 reaching €52.99m (DKK 395m at a rate of 745.45).³² 95% of these savings – or, €50.36m - come as direct savings, with the remaining €2.63m attributed to estimated indirect savings.

In Denmark, the bulk of direct savings have traditionally been derived from a narrow number of drugs, reflecting a very concentrated market. For example, in 2009 the top ten PI drugs contributed to 63% of overall savings. However, in 2011 this figure is down to 27%, reflecting the wider array of PI drugs in a more diversified market.

In 2011, the share of total drug expenditure spent on parallel imported products in Denmark grew to 24%.

8. Germany

The methodology for determining *direct* savings from parallel distributed medicines evaluated by Prof. Pedersen consists of establishing the total number of packages of PI dispensed, multiplied by the price difference between the parallel import and the corresponding originator product. Starting from 2009, Germany has seen several significant government interventions into medicinal pricing and reimbursement, often followed by corrective measures to fix unforeseen results. As a consequence,

³⁰ Data provided by the Latvian member of the EAEPC

³¹ http://ec.europa.eu/competition/ecn/brief/01_2011/lv_medicine.pdf

³² Throughout most of the 2000s, direct savings in Denmark hovered around the 15m euro mark.

exact calculations *at present* are impossible as price differences between originator and corresponding PI medicines have to be established *including* the new mandatory discounts (introduced by German law in 2010); unfortunately, these amounts have not been and are (still now) not correctly calculated by the responsible German institutions.

Instead, this update report is turning to an **estimate** based on IMS turnover data of parallel imports in Germany from 2009 (the last year for which exact calculations are possible and have been made) to 2012, and calculates from these amounts the savings proportionally.

In 2009 direct savings of 289 mio € were generated (see Pedersen Update, p. 9). The following table illustrates the result of these turnover-based estimates from 2010 to 2012.

	2009	2010	2011	2012 *
Total PI turnover in Germany at manufacturers prices	2,891,392	3,285,608	2,857,445	2,941,947
Savings calculated on 2009 figures ratio	289,000	328,403	285,607	294,053

* 2012 figures extrapolated from currently available 1-11/2012 turnover - Turnover database: IMS

All figures in mio €

Regarding *indirect* savings in Germany, the reference price mechanism applied across Europe creates a significant resistance of drug manufacturers to give in to price pressure in a high-price market in order not to suffer ripple effects in other markets. The industry association Efpia has recently drawn attention to this knock-on effect, in the context of repeated price cuts in Greece³³.

³³ "Ignore our drug prices", Greece tells Europe, Scrip, 21 December 2012 No 3630

9. Sweden

The market in Sweden has significantly changed with the liberalisation of retail pharmacy in Sweden in 2009-10. The deregulation had several objectives: to achieve efficiency gains, better accessibility for consumers, price pressure, and safe and appropriate use of medicinal products. Targets have been achieved, with approximately 330 new pharmacies opening on the Swedish market since the deregulation took effect³⁴. The liberalisation has also significantly changed the conditions for parallel imported medicines.

In the course of the debate leading towards liberalisation of retail pharmacy, policymakers accepted that the sell-off by the former state monopoly Apoteket of some two thirds of its retail outlets and the creation of privately held pharmacy chains will require a financial incentive in order for the new retail distribution network to be viable. So, the new pharmacy owners were given the option to negotiate purchasing prices for parallel imported drugs with suppliers.

At the same time, reimbursement prices at pharmacy level were set to be the same for domestically sourced medicines as for parallel imports, leaving the pharmacies an extra margin for sourcing cheaper parallel imports. The official pharmacy purchase price (AIP) is the basis for the reimbursement and is unaffected by discounts obtained from PI. This means that the state no longer accrues direct savings to the health insurance, but enjoys the indirect effects of better market conditions for pharmacies.

The official pharmacy purchase price is 'static' as long as there is no generic competition within the substitution group. Any discount on parallel imports is negotiated on the AIP that works as a "ceiling price". Strong price competition between parallel distributors is therefore characteristic of the Swedish distribution system.

This market mechanism has proven successful in that the share of parallel imported medicines in the pharmacy (excluding hospitals) has grown from a level around 10-11% at the time of liberalisation to close to 20% in 2012. It should be noted that in this period exchange rate fluctuations (SEK vs GBP or €) have also played in favour of increasing parallel imports. The government appears to have been surprised by its own success and is considering scaling the incentive back.

As a way of comparison, in the UK the reimbursement model also allows pharmacy the freedom to purchase medicines at the lowest available price, against National Health Service set reimbursement prices independent of the source of medicines. Any excess benefit of pharmacy as a whole is subject to a claw-back, instead of an intervention into market prices or prescribing practise.

³⁴ The Swedish Agency for Growth Policy Analysis - Development of the cost of pharmaceuticals in the deregulated pharmacy market, Report 2012:13 page 9-10, www.tillvaxtanalys.se

10. United Kingdom

Following the dip in UK direct savings experienced in 2009, where €65m of savings were recorded, figures for 2010 and 2011 show a slight upward curve. The UK parallel import industry generated direct savings of €75m in 2010, and €85m in 2011.³⁵

The share of PI sales as a percentage of total pharmaceutical shares rose steadily from its 2009 figure of 6,1%, to 6,4% in 2010, 7.0% in 2011 and 7.5% by mid-2012. However, the share of parallel imported units sold - as a percentage of the total number of pharmaceutical units sold - remains steady at 2%.

³⁵ Data provided by the UK member of the EAEPC. Original direct savings figures of £64,7m in 2010 and £71,3m in 2011 were converted to euros using the rate at 31 December of the respective year.

Conclusion

The main findings from the six markets covered in this report can be summarised as follows:

- In five of the six markets (apart from The Netherlands) there is a higher indirect to direct savings ratio, which can be mainly explained by the relatively small size of PI market in each of those countries, and therefore a lack of regular and enshrined negotiations with governmental authorities.
- Downward pressure on originator drugs has led to large savings in France, Poland as well as in Ireland, whilst in the case of Italy, PI have had a stabilising affect on originator price increases on the Italian market.
- Direct savings have increased in France in recent years, almost doubling from 2010 to 2011, while direct savings in Poland reached €6m in 2009 and in Ireland, €4.18m in 2011. Furthermore, best estimates note that direct savings in The Netherlands in 2010 reached €12.75m.
- Additional factors contributing to further savings include (in both the case of France and Ireland) actions taken by social security systems on negotiating with parallel distributors lower reimbursement prices than those at which originators are reimbursed, thus contributing to generating further savings for healthcare systems in these countries.

Parallel distribution can only exist where there is demand, and demand would not exist if the parallel distributor did not pass on a large part of the price differential to those actors paying for the medicines. The price charged for a parallel distributed product is always less than that for the domestic version. If this were not the case, the entire *raison d'être* of parallel distribution would disappear. There is therefore not only a good rationale but also an economic theory that supports the development of such practices, beyond the traditional markets that were usually analysed in the past.

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