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Parallel Import of Pharmaceuticals in the EU

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Abstract

Parallel import in the European Union is the perfectly legal activity under Art. 28-30 EC of buying goods in a low-price country in order to ship and sell them in a high-price country. The pharmaceutical market in Europe is subject to the subsidiarity principle of Art. 5 EC and heavily characterised by national regulations that lead to significant price differentials between – generally speaking – Northern and Southern Europe. This incites the activity of parallel traders in the first place, who act as arbitrageurs. Since their operations have the effect of counteracting the partitioning of national markets, they are favoured by the European Community as a means of market integration.

Though the legal background is clear-cut, the situation is more ambiguous from a socio-economic and political perspective. In terms of global competitiveness in the pharmaceutical sector, Europe still lags behind the US which calls for the need of increasing investment in research and development. Parallel trade has however a negative effect on the research-based industry as it leads to a direct shift of profits from the patent holder to the parallel trader.

On the contrary, the distribution of less expensive parallel imports is a measure of cost containment in importing countries since it leads to savings in pharmaceutical expenditure for public health care payers and patients. This is particularly important as both health care and pharmaceutical spending are continuously growing across countries and call for means of cost control. Especially in the last decade, Member States have been characterised by constant efforts to reform the health care sector as a way to limit expenditures.

However, long-term effects in high-price countries as well as impacts on consumers in exporting countries are ambiguous. They consist of lower investment in research and development which, in turn, negatively affects the generation of innovative and cost-effective drugs, the delay or failure of product launches in low-price countries as well as product shortages in the latter. Furthermore, other stakeholders such as physicians and pharmacists are involved in parallel imports through the obligation by legal measures. Seldom are they incited economically, yet their status as decision makers for the patient is crucial for the successful distribution of parallel imports.

The aim of this thesis is to identify legal and economic incentives for stakeholders to engage in parallel imports and to quantify their benefits and costs that arise through parallel trade. This is done by looking more closely at two importing and two exporting countries. Germany and Sweden as importing countries show interesting opposite developments in parallel imports in a differing regulatory environment which allows the conclusion on inciting measures. Greece and Spain are the largest exporting countries in Europe, where the effects of parallel trade are more transparent to be identified than in other countries.

The stakeholder analysis shows that the benefits of parallel trade accrue mainly to the parallel importer and are, in comparison, minor for public payers and patients. Furthermore, these benefits cannot justify their negative impacts particularly on consumers in exporting countries. Even if they are a means of market integration, they do not lead to a natural competitive environment due to the regulation of national markets.

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Så ball så, nu är det dags för karneval!

Lund, May 15th, 2006

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LIST OF ABBREVIATIONS

AABG	Arzneimittelausgaben-Begrenzungsgesetz (Pharmaceutical Expenditure Limitation Act, Germany)
AG	Advocate General
AMG	Arzneimittelgesetz (Law on Medical Products, Germany)
ATC	Anatomical Therapeutic Chemical
AVWG	Gesetz zur Verbesserung der Wirtschaftlichkeit in der Arzneimittelversorgung (Law on the Improvement of Efficiency in Drug Supply, Germany)
AZ	AstraZeneca
BPI	Bundesverband der Pharmazeutischen Industrie e.V. (German Federal Association of the Pharmaceutical Industry)
CEEC	Central and Eastern European Countries
CFI	Court of First Instance
EAEPC	European Association of Euro-Pharmaceutical Companies
ECJ	European Court of Justice
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMEA	European Medicines Evaluation Agency
EU	European Union
GSK	GlaxoSmithKline
GW	GlaxoWellcome
IMS	Intercontinental Medical Statistics
IPR	Intellectual Property Right
LFI	Läkemedelsindustriföreningen (The Swedish Association of the Pharmaceutical Industry)
LFN	Läkemedelsförmånsnämnden (Pharmaceutical Benefits Board, Sweden)
MEQR	Measures having Equivalent Effect to Quantitative Restrictions
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
PI	Parallel Import
PT	Parallel Trade
R&D	Research and Development
SHI	Statutory Health Insurance
VFA	Verband Forschender Arzneimittelhersteller e.V. (German Association of Research-Based Pharmaceutical Companies)
YHEC	York Health-Economics Consortium

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1 Introduction

1.1 Problem Formulation and Objective

Pharmaceutical parallel imports is the completely legal activity of importing patent protected drugs into another country where the same product has been registered and is marketed without the consent of the patent holder. In its Communication on the Single Market in Pharmaceuticals, the European Commission states that

“Parallel trade acts as an important driving force for market integration where there are important differences in prices between Member States. These differences must be addressed in a way that is consistent with the principles of the Single Market and cannot justify measures the effect of which is to maintain or increase the partitioning of the common market along national lines.”¹

This apparently clear-cut positioning of parallel trade is, however, not as clear-cut as it seems. Indeed, a rather complex situation arises due to three conflicting EU policy goals. Firstly, the subsidiarity principle inherent in the Treaty in Art. 5 EC ensures the autonomy of Member States in health policy and thereby enables price differentials on the market. This generates parallel trade in the first place as it only arises due to significant differences in national legislation on pricing

Secondly, the principle of free movement of goods which is established in Art. 28-30 EC and the case law established by the European Court of Justice (ECJ) clearly state the legitimate nature of parallel trade and hence of the price arbitration by parallel importers. Furthermore, as their activity leads to alleged price convergence of national prices, parallel traders are perceived as a means of market integration by the European Commission.

Last but not least, the objective of the Lisbon strategy – though of mere political nature – is to render the EU into the most competitive and dynamic knowledge based economy, implying the encouragement of innovations in high-technology intensive sectors such as pharmaceuticals. Emphasis is thereby laid on the fact that the EU still lags behind the US in terms of research and development (R&D) investment and success. Only 19% of new medicines marketed are generated in Europe, opposed to 70% in the US. Europe has the second largest pharmaceutical sector in the world with an average annual growth of 7.3% but is, however, growing at a slower pace than the US market.

¹ Commission Communication on the Single Market in Pharmaceuticals COM (98)588 final, 25 November 1998, p 20

The situation is further complicated by the controversial economic impact of parallel trade in terms of their benefits and cost for stakeholders. Its effects on welfare are ambiguous depending whether they are viewed in the short term or long term. Whereas they seem advantageous for public health payers and patients at first glance as they accrue to savings in pharmaceutical spending, the situation is different when the entire circumstances are taken into account such as the supply situation of the exporting country and long-term impacts on R&D. According to the economic theory of Ramsey-pricing, it is not even desirable to establish harmonised prices as price differentials take price sensitivities, purchasing powers and income levels into account and therefore allow the most efficient partition of joint R&D costs.

The average rate of parallel imports in the European Union amounts to 5% (2003) but varies highly between countries. Major affected countries are traditional high-price countries such as the UK, Denmark, the Netherlands, and Germany, but also Sweden which ranges more in the middle of European countries in terms of average drug prices. The largest exporting countries are Spain and Greece with the traditionally lowest prices on the European market, Greece having a peak parallel export rate of 24.1% in 2001. The situation of parallel imports on the national markets changed however over recent years. Whereas Sweden is a country with a high and constantly increasing level of parallel imports of 12.2% in 2005, Germany – though having higher prices than Sweden – has a comparatively very low level of parallel imports which were actually decreasing in recent years to 4.9% in 2004.

The focus in the analysis shall be put on four European countries, i.e. Sweden and Germany as parallel importing countries but with different allocations on a scale of average prices, and Spain and Greece as low-price and parallel exporting countries. The former two have been chosen because they show an interesting contrasting development and allow an analysis of legal measures and economic circumstances working as an incentive or disincentive for parallel imports. The latter two countries represent undisputedly the Member States with the highest parallel export rates and lowest prices which allows an illustrative comparison.

The objective of this thesis is to discuss the impact of parallel imports in pharmaceuticals on different stakeholder groups in terms of legal and economic incentives as well as economic benefits and costs. Stakeholders are defined here as those directly or indirectly affected by parallel trade and shall be identified as parallel traders, public payers in the national health care system, consumers, pharmacists, physicians, the research-based industry and the European Commission. The latter is in contrast to the other stakeholders not direct subject to economic impact or concerned by legal measures, yet it has an interest in parallel trade as a means of market integration. The analysis aims at determining positive and negative effects on stakeholders and at illustrating the trade-off between a short-term and a long-term reflection both in high-price and in low-price countries. Gains and losses are quantified as far as possible, relying on recent studies (see Chapter 1.2). The questions to be answered include who the real beneficiary of parallel trade is and whether short-term benefits can be maintained in the long run.

1.2 Research Method

The thesis combines the use of primary and secondary data. Primary data was thereby collected in the form of qualitative method, i.e. personal interviews. They were conducted with the following persons (in chronological order):

- Colin Mackay, Weber Shandwick, Brussels, on February 20th, 2006, duration ca. 20 minutes;
- Nicola Schelling, DG Competition, European Commission, Brussels, on February 21st, 2006, duration ca. 70 minutes;
- Juliana Frendo and Florian Schmidt, DG Enterprise, European Commission, Brussels, on February 24th, 2006, duration ca. 45 minutes;
- Verena Wulf and Monika Scheuermann, Johannis-Apotheke, Hamburg, on April 27th, 2006, duration ca. 20 minutes;
- Marie Sörensson and Katarina Magnusson, Apoteket Svanen, Lund, on May 3rd, 2006, duration ca. 20 minutes.

Furthermore, I had email contact with Monika Dahl of the Bundesministerium für Gesundheit (Federal Ministry of Health, Germany), Pernilla Agardh of Nordic Drugs AB, and Kirsten Overgaard of Novo Nordisk A/S. Though not all interviews are cited, they helped me

significantly to get a precise and structured picture of the topic as well as the views and stakes of stakeholders. The utilised secondary data consists mainly of academic articles and books as well as statistics published by different associations.

Chapters 2 and 3 are based on academic literature, mainly from specialised reviews, and on statistics. I did not have direct access to the IMS data which is the most important source of statistics in pharmaceuticals, the statistics cited are based on publications by different associations who in turn base them on IMS or OECD data.

Part 4 on national pricing and reimbursement measures is based both on publications and on national legislation. Since it was sometimes quite difficult to identify if the measures were still up to date or who they addressed, some primary research was conducted here for clarification purposes.

In Chapter 5 on relevant European Community law I applied traditional legal method, using both primary and secondary legislation, i.e. the EC Treaty, relevant case law and regulations and directives with regard to parallel imports. The choice of case law is mainly based on recent literature published in that field² and updated on recent developments. Beginning with the analysis of Treaty principles, the research is further oriented at significant cornerstone judgments in the area of parallel trade.

The stakeholder analysis is based on the data analysed in the preceding chapters and therefore also based on the respective literature. Quantifications in terms of benefits and losses are based mainly on three recent empirical studies, i.e. Kanavos et al (2004)³ and YHEC (2003)⁴ and Persson et al (2001)⁵. The data has however to be seen as an indicator as study results differ considerably though the former two were both conducted in 2002. Furthermore, along with this factual data, arguments of the stakeholders and their subjective interests are identified also by analysis of their company presentations on the internet and by personal interviews.

² Hays, Th. (2004), "Parallel Importation under European Union Law", Sweet & Maxwell, London; Hunter, R. (2001), "The pharmaceutical sector in the European Union- Intellectual Property Rights, parallel trade and competition law", Institutet för Europeisk rätt vid Stockholms Universitet, Stockholm; Farquharson, M. and Smith, V. (1998), "Parallel Trade in Europe", Special Report, Sweet & Maxwell, London

³ Kanavos, P., Costa-i-Font, J., Merkur, Sh., and Gemmill, M. (2004), "The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis", London School of Economics

⁴ West, P. and Mahon, J., Youth Health Economics Consortium (YHEC) (2003), "Benefits to payers and patients from parallel trade", University of York

⁵ Persson, U., Anell, A. and Persson, M. (2001), "Parallellhandel med läkemedel i Sverige – en ekonomisk analys", The Swedish Institute for Health Economics, Lund

1.3 Outline

The thesis is organised as follows. In Chapter 2, the economic aspects of parallel trade are presented and touch both upon the economic motivation for parallel trade as well as its economic and welfare implications. It becomes apparent that a distinction has to be made between the benefits of parallel trade in general and in a highly research intensive industry as pharmaceuticals. In particular, the centre of interest is the alleged benefits in terms of higher welfare and the distinction between short-term and long-term effects.

Chapter 3 aims at providing an ample picture of the European pharmaceutical market in relation to parallel trade. Besides the analysis of the relevance and current level of parallel imports, the pharmaceutical sector is characterised in general and particularly in relation to factors highly relevant in parallel imports such as R&D, price structures and pharmaceutical spending. In order to embrace the accession of the new Member States in 2004 and to provide an outlook on potential future sources of parallel trade, the data provided includes the two largest Eastern European countries Hungary and Poland as far as it was available in addition to the four countries of focus.

National regulations on pricing and reimbursement of pharmaceutical products as well as national policies on parallel imports are matter of interest in Chapter 4. Whereas the former represent first of all legal measures that entail a direct economic incentive for parallel trade, the latter are measures that are directly or indirectly related to it and embody obligations for certain stakeholders to (potentially) engage in parallel trade.

Parallel imports are finally put in the legal framework of European Community law in Chapter 5. Two main provisions are relevant here, i.e. the principle of free movement of goods inherent in Art. 28-30 EC and the competition provisions Art. 81 and 82 EC. They are analysed in context with the case law of the ECJ which clearly established on the one hand their legality and, on the other hand, which measures of pharmaceutical companies to counteract parallel trade are not in breach of the Treaty provisions.

The sixth chapter finally contains the stakeholder analysis based on the foregoing chapters. As actors impacted by or engaged in parallel trade, parallel distributors, public health care payers, consumers, pharmacists, the research-based industry and the European Commission are analysed with regard to their legal and economic incentives and interest as well as to their costs and benefits. The thesis is rounded by an overall conclusion in the last chapter which summarises and reflects on the results of the foregoing chapters.

2 Economic Aspects of Parallel Trade

2.1 General Definition and Rationale of Parallel Import

Parallel importation can be defined as the legitimate process of purchasing goods that are legally protected by intellectual property rights (IP rights) such as trade marks, copyrights or patents in one market (home market, low-priced) in order to import them into another market (foreign market, high-priced) against the will of the IP right holder. They are then sold at competing prices which are lower than the prices of the goods sold directly by the IP right owner in the second market.^{6 7}

The rationale of parallel imports is the exploitation of price differentials between identical products on different markets. The parallel importer thereby establishes an alternative supply network which counteracts the distribution channel of the IP right holder and makes his profits as an arbitrageur to the detriment of the latter. The price differentials result partly from factors such as technological specifications and regulatory requirements, e.g. obtaining market authorisation, and partly from differences in income levels and purchasing power. They are complemented by determining variables to different extents such as transaction costs, technical barriers, trade policy, intensity of competition on the national market, vertical constraints, and previously existing parallel trade. These can either incite or discourage parallel trade. The importance of a variable is strongly related to the nature of the imported product and its commercial sector. For example, transportation costs are of major importance in parallel trade of motorcars or consumer electronics, whereas they are almost insignificant in goods such as musical records or pharmaceuticals.⁸ Hedging against exchange rate differentials plays only a role in non-Euro countries.⁹

Due to its nature, that is, in circumventing conventional and intended trade by the IP right holder, parallel imports always has the negative connotation of unlawfulness. However, several rulings by the ECJ confirm and emphasise their perfect legality.¹⁰ They are furthermore not only encouraged by the European Commission, but also by several Member States.¹¹

⁶ Hays (2004), pp 1-5

⁷ Ganslandt, M. and Maskus, K. (2004), "Parallel imports and the pricing of pharmaceutical products: evidence from the European Union, *Journal of Health Economics*, Vol. 23, pp 1035-1038

⁸ National Economic Research Association (NERA) (1999), "The economic consequences of the choice of a regime of exhaustion in the area of trade marks: Final Report for DGXV of the European Commission"

⁹ Kanavos et al (2004), p 18

¹⁰ Farquharson and Smith (1998), pp. 1-6

¹¹ Kanavos et al (2004), p 17

2.2 Economic Motivation for Parallel Imports

IP right holders are, by definition, monopolists who would like to set prices in different markets with different elasticities of demand in a manner that allows them to obtain the highest profit possible. If the monopolist can maintain geographical market segmentation, he is able to charge higher prices in markets with lower demand elasticity (third degree price discrimination, i.e. market or customer segmentation). Parallel imports counteract this ability and lead in theory and on competitive, unregulated markets to uniform pricing.¹²

Supposing that the market demand is unlimited and perfectly elastic, to prevent potential arbitrage, the IP right owner can block parallel imports by establishing an arbitrage free price in the foreign market, i.e. a price that does not allow the parallel trader to both cover his costs and generate profits. Though the price does not have to be identical to the price in the country of parallel exportation, it can be described as uniform pricing as the prices will be very similar. This is advantageous for the IP right holder in the sense that he will not lose further market share to parallel importers. Under an arbitrage situation, the IP right holder would assumingly sell the same quantity in the low-priced home market to the parallel trader which he now can sell directly instead in the foreign market at a higher, though arbitrage free price.¹³

However, parallel trade can be characterised as “imperfect arbitrage” since it does not only involve a certain risk, but also transaction costs which are greater than zero. In order to be profitable for the parallel trader, the sales price for the parallel import products in the foreign market has to cover both the cost of purchasing products in the home market as well as trading costs and has to generate profits for the parallel trader. In contrast to “pure” arbitrage, (pharmaceutical) parallel trade results from heterogeneous regulations in different Member States. Economic theory predicts that in unregulated markets with perfect competition and absence of product differentiation, arbitrage would lead to price competition with a “race towards the bottom” which would, in the end, lead to price equalisation of different markets and create one single market. In contrast, as long as regulatory differences prevail, price equalisation is unlikely to occur. With regard to the regulatory situation on the national pharmaceutical markets in Europe which are characterised by national autonomy and partly

¹² Kanavos et al (2004), pp 26-27

¹³ Ganslandt and Maskus (2004), p 1042

strong political influence of sickness funds as monopsonistic buyers, and the industry players, price harmonisation seems very improbable.¹⁴

Furthermore, (pharmaceutical) parallel trade is characterised by a lack of vertical control in the distribution chain, which is mostly due to the prohibition of vertical agreements in Art. 81.1 EC that makes it impossible for producers to control their distribution channels as this would be considered as anti-competitive behaviour. Wholesalers are more or less free to distribute their supplies to parallel traders instead of delivering it to the domestic market.¹⁵

2.3 Economic and Welfare Implications of Parallel Trade

The economic implications of parallel trade are ambiguous depending on the angle from which they are seen. In the short run, parallel imports might well lead to consumer benefits in high-price markets as price convergence between countries leads to lower prices for them. On the other hand, this also implies price increases in low-price countries and therefore losses for those consumers and, in any case, losses for the producer which signifies reduced possibilities for R&D funding.

Furthermore, although decreasing prices in high-price countries might seem advantageous for the consumer on the first glance, a distinction between short-term and long-term perspective has to be made. First of all, the benefits of parallel trade are mainly inherent in a pure shift of profit from the manufacturer to the parallel trader which implies the shift of funds forgone from research-based companies to non-research-based companies.¹⁶ The end consumer and even pharmacists, sickness funds and public bodies only benefit to a degree that the parallel trader allows them to by setting his distribution margins just low enough to reflect the lower prices of the exporting country. Depending on reimbursement policies and co-payments, the end consumer might not benefit at all. Savings in the short run resulting from lower prices may lead to disadvantages in the long run since reduced profits lead to lower investment in R&D activities which, in turn, trigger the development of fewer drugs. Price convergence or uniform pricing on the European pharmaceutical market is not a panacea but only a short-term – and maybe short sighted – remedy to outcast national fiscal problems and to cater to cost control in the health care sector.

¹⁴ Kanavos et al (2004), pp 24-25

¹⁵ Ibid, p 25

¹⁶ Ibid, p 34

Parallel trade in pharmaceuticals does not yield the same efficiency gains that result from normal free trade. The latter usually increases welfare due to importation of goods which are produced more efficiently or at lower cost in the exporting country. In the pharmaceutical sector, however, savings in production costs are insignificant compared to the heavy investment in R&D, and parallel trade only exploits different national pricing regulations and does not promote more efficient production.

Pharmaceutical R&D is, in economic terms, a '*global joint cost*' that benefits consumers worldwide and stays the same regardless of the number of consumers or countries served. The most efficient way to cover joint costs and to obtain the greatest global social welfare is so-called *Ramsey-pricing* which concludes that it is more efficient to charge different prices to different users when they differ in their true price sensitivity (elasticity). In other words, in order to maximise global welfare, the mark-up of prices over marginal cost should be greater in countries with relatively low-price sensitivity (inelastic demands) than in countries with high-price sensitivity (elastic demand). This allows for each customer group to lower their demand by an equal percentage opposed to uniform pricing where customers with high-price sensitivity will reduce their demand more than others and hence suffer a greater loss in welfare. As long as price sensitive customers pay for prices that cover their own marginal costs plus some contribution to the joint costs, the higher price for price insensitive customers can still be lower than would be required for to maintain the same rate of innovation without the contribution of low-price customers as in uniform pricing. Consequently, not only global social welfare is greater at Ramsey pricing but also the level of R&D activity because manufacturers receive higher return on sales with differential pricing. Hence, parallel imports undermine the most efficient pricing mechanism to recover R&D costs.¹⁷ Furthermore, demand for pharmaceuticals has been measured to be less price sensitive than the demand for other goods because they are highly valued for their preventive or health-producing effect.¹⁸ Uniform pricing which would lead to higher prices in current low-price countries is therefore also from a social point of view not sustainable as patients would be forced to spend a higher percentage of their income on medication which exceeds their purchasing power, or switch to cheaper but less effective alternatives.

¹⁷ Danzon, P. (1998), "The economics of parallel trade", *Pharmacoeconomics*, Vol. 13, No. 3, pp 293-304

¹⁸ Vogel, R. (2004), "Pharmaceutical pricing, price controls, and their effects on pharmaceutical sales and research and development expenditures in the European Union", *Clinical Therapeutics*, Vol. 26, No. 8

The problem of joint costs is that they are largely sunk by the time the product is launched on the market and price negotiations with national authorities take place. Since public health care systems are mostly run by governments, it is basically the only purchaser and therefore has a monopsonistic negotiating power with the tendency to drive prices towards marginal costs. Its position is strengthened by the fact that any manufacturer will continue to supply as long as prices cover marginal costs and allow him to survive in the short term. To reward producers for their innovation activity and to protect them from competitive prices which would prevent them to regain their R&D costs, patents are granted as, basically, the “legal grant of limited market exclusivity”¹⁹. However, in practice their market power is constrained on the one hand by similar but therapeutically and chemically distinct substitutes which often already occur within several months after the product launch, and on the other hand by the national exhaustion of IP rights, as the ECJ established in *Merck v Stephnar*²⁰. National price regulations further constrain the free use of patent power.²¹

Hence, manufacturers are in practice not as free in their monopoly power as economic theory suggests. Yet they still need incentives to develop innovative drugs which implies that global revenues have to cover long-term costs, including joint (sunk) costs of R&D. Parallel trade not only exports products, but also their lower prices. Through a relatively fast diffusion of these lower prices, the free-riding of smaller countries can trigger a significant erosion of global revenues and of R&D incentives. It becomes apparent that it is the global nature of pharmaceutical joint costs that makes the industry more vulnerable to downward biased regulation than other regulated industries: Pharmaceutical producers are faced with mostly intangible R&D capital and cannot allocate costs to specific countries where they are faced with regulations.²²

¹⁹ Danzon (1998), p 296

²⁰ Case 187/80 *Merck & Co. Inc. v Stephnar BV and Petrus Stephanus Exler* [1981] ECR 2063

²¹ Danzon (1998), pp 295-296

²² *Ibid*, p 297

3 The Pharmaceutical Industry in Europe in Figures

This chapter's objective is to provide the reader with a comprehensive background on the European pharmaceutical market, focusing on features that are important for parallel imports. Besides general economic indicators such as production, value added and employment, R&D characteristics in pharmaceuticals and the significance of pharmaceutical expenditure shall be summed up and put into a global context. Subsequently, generic products, price structures and indicators on parallel imports will be looked upon, focusing on the European market and in particular Germany, Sweden, Spain and Greece.

3.1 General Economic Indicators

With pharmaceutical sales of US \$ 169.5 billion which constitute 30% share of global sales (US \$ 566 billion), Europe is the second largest region of sales worldwide behind the US (US \$ 265.7 billion, i.e. 47%) and followed by Japan (US \$ 60.3 billion, i.e. 11%, see *Figure 1*).²³ As one of Europe's best performing high-technology sectors, the research-based pharmaceutical industry is a key asset to the European economy. Pharmaceutical production in Europe²⁴ amounted to € 157,451 million in 2003, with exports of € 149,904 million and imports of € 114,384 million.²⁵

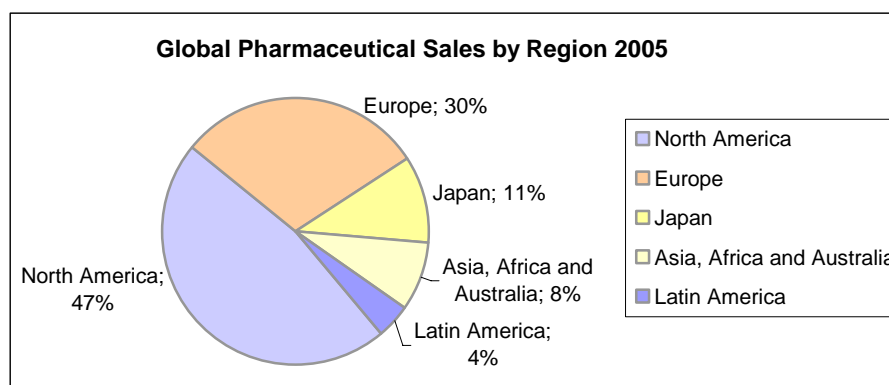


Figure 1: Global Pharmaceutical Sales by Region 2005
Source: IMS Health

²³ IMS Health (2006)

²⁴ EU-15 ex Luxembourg plus Switzerland, Norway, Hungary and Poland

²⁵ EFPIA (2005), "The pharmaceutical industry in figures – key data, 2005 update", Brussels, available online at www.efpia.org, accessed 04/02/2006

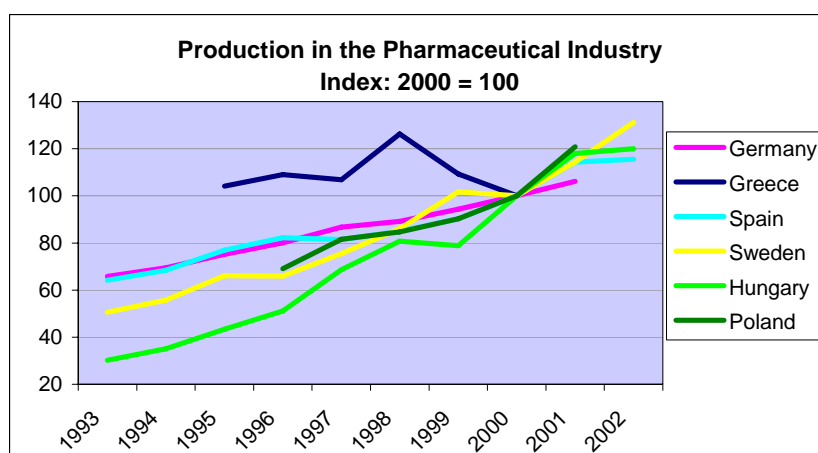


Figure 2: Development of Production in the Pharmaceutical Industry 1993-2002
Source: OECD 2006

Million EUR	Production	Value Added (2002)	Export	Import
Germany	21,262	*10,024	21,035	18,387
Spain	9,374	2,941	3,876	6,534
Sweden	5,758	**3,898	5,838	1,972
Poland	*1,531	555	295	2,627
Hungary	*1,288	677	832	1,149
Greece	437	**137	530	1,886
Europe Total 2003²⁶	157,451	18,232	149,904	114,384

Table 1: Pharmaceutical Production, Value Added, Exports and Imports 2003 in Million EUR
Source: EFPIA 2005 and OECD 2006. (* 2001; ** 2000)

Between 1993 and 2003, the European pharmaceutical market grew at an average rate of 7.3% per annum compared to the US market which increased by 11.9%.²⁷ Pharmaceutical production has strongly increased in the United Kingdom, Sweden and Denmark, which continuously promoted their R&D activities for many years. In contrast, production in Germany increased at a lower growth rate and even decreased by 1% in 2004.²⁸ Among the new EU member states, Hungary and Poland have the largest total sales and show a strong increase in production (see *Figure 2* and *Table 1*)²⁹. Intercontinental Medial Statistics, IMS, estimate an average annual growth of 8% in Poland and 14.4% in Hungary for the next five years. Though they currently only constitute 6% of the pharmaceutical market volume in Europe, the ten new EU countries are expected to grow at above-average rate.

²⁶ EU-15 ex Luxembourg plus Switzerland, Norway, Hungary and Poland

²⁷ EFPIA (2005)

²⁸ Verband Forschender Arzneimittelhersteller (VFA) (2005), "Statistics 2005 – The Pharmaceutical Industry in German", Berlin

²⁹ Czech Republic closely follows with total sales of €1,024 million (2003). However, no other numbers were available.

In 2003, 586,748 persons were employed in the pharmaceutical industry in Europe (Table 2), thereof every sixth person worked in R&D (99,337 employees).

Employment in the Pharmaceutical Industry (headcounts) 2003	
Germany	119,800
Spain	39,000
Sweden	21,600
Greece	11,200
Europe Total³⁰	586,748

Table 2: Employment in the Pharmaceutical Industry (absolute) 2003
Source: EFPIA 2005

The increase in value added (GDP by industry)³¹ of the pharmaceutical sector differs across countries. Whereas it has grown at a considerably slower rate than production in Sweden and in Germany (though less significant), value added has grown at a faster pace than production in Spain. In Greece, Hungary and Poland, variations in these indicators were correlated (see Figure 2 and Figure 3). In any event, the pharmaceutical industry in Europe is among the best performing and most productive industry sectors. It contributes 3.5% of the total EU manufacturing value added and about 17% of total EU business R&D expenditure (behind the automobile industry with 23.8%).

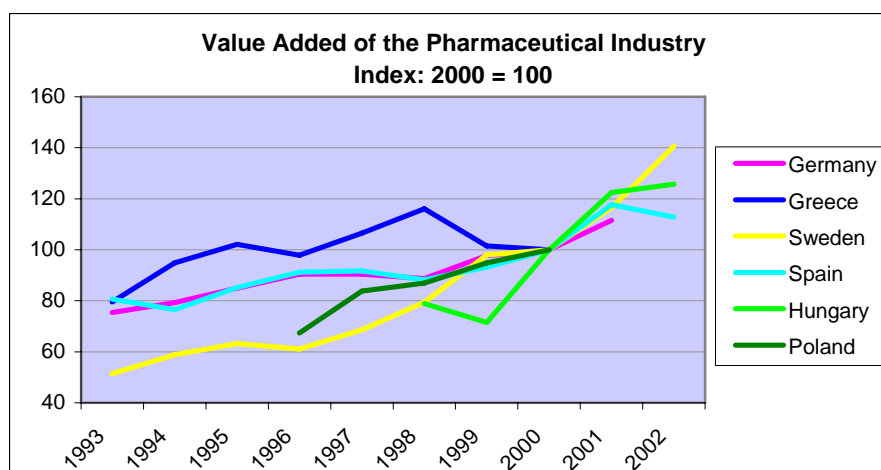


Figure 3: Value Added of the Pharmaceutical Industry 2003
Source: OECD 2006

³⁰ EU-15 ex Luxembourg plus Switzerland and Norway

³¹ Value added for a particular industry represents its contribution to national GDP. It is not directly measured. (OECD 2006)

3.2 Research and Development

One of the key points in the discussion about parallel trade is the argument put forth by the research-based industry that lost profits from parallel imports affect investments in R&D and incentives negatively. Innovations in pharmaceuticals concern mainly the discovery and development of new chemical and biopharmaceutical entities that become new therapies. R&D is a very costly and lengthy process of which the fruits cannot be fully yielded for many years. Uncertainties in the R&D processes result in many expenditures on projects that in the end will not lead to marketable products and necessitate the allocation of costs for unsuccessful projects on those that result in marketable products. Research in the field of genomics and other new technologies is furthermore expected to lead to a major increase in R&D costs in the future as the research targets are not yet well understood.³² A recent examination between the profitability and investment in R&D found a high degree of correlation between deviations from trend for the time series on R&D expenditures and on gross margins. This suggests that R&D outlays are affected significantly by changes in profitability with delayed effect. As growth rates for gross margins in recent years were substantially lower than growth rates for R&D expenditure, this leads to the assumption that R&D investment could lessen in the future.³³

In a global comparison, Europe still lags behind the US in terms of R&D investment. Whereas it grew by 2.7 times in Europe between 1990 and 2004, it increased by 4.5 times in the US. The latter had a share in worldwide R&D expenditures of 47% in 2003, followed by Europe with 40% and Japan with 13%. The share of the US keeps further increasing. Of new medicines marketed from 1999 to 2003, 70% of were generated on the US market, opposed to only 19% of European origin (Japan: 4%).³⁴

The cost of researching and developing a new chemical or biological entity was estimated to amount to € 870 million in 2001, compared to € 344 million in 1987.³⁵ Furthermore, on average only one or two out of 10,000 screened and synthesised substances will be successful in passing all stages of R&D, clinical trials and be a marketable medicine. Though patent protection lasts for 20 years, 12 to 13 years pass on average from the synthesis of the new active substance to the time the actual product is marketed (ten years of R&D plus two to

³² DiMasi, J., Hansen, R., and Grabowski, H. (2003), "The price of innovation: new estimates of drug development costs", *Journal of Health Economics*, Vol. 22, pp 151-185

³³ Scherer, F. (2001), "The link between gross profitability and pharmaceutical R&D spending", *Health Affairs*, Vol. 20, No. 5, pp 216-220

³⁴ EFPIA (2005), VFA (2005)

³⁵ DiMasi et al (2003)

three years of administrative procedure, i.e. registration/market authorisation, pricing, reimbursement, pharmacovigilance). A supplementary protection certificate can be obtained for a maximum of five years.³⁶

Pharmaceutical R&D Expenditure in million €, 2003	
Germany	3,820
Spain	610
Sweden	1,030
Greece	36
Europe Total³⁷	20,495

Table 3: Pharmaceutical industry R&D in Europe 2003
Source: EFPIA 2005

Total investment in R&D in Europe amounted to €20,495 million in 2003. In comparison to the US, Europe is perceived as less attractive for R&D investment in terms of market conditions and incentives for the creation of new biotechnology companies.

3.3 Health Expenditure and Pharmaceutical Spending

In most European countries, health care expenditure and pharmaceutical spending as an important part of it has constantly increased since the 1960s, particularly from the 1980s on. On European average, 8.4% of the GDP were spent on health care in 2002. Germany and Switzerland range at the top level with over 11% health care spending in Europe and worldwide just behind the US. *Figure 1* shows expenditures of Germany, Sweden, Greece and Spain as well as of Hungary and Poland. Whereas Hungary comes close to the average OECD of 8.8%, Poland ranges among the five lowest spending countries. There is a positive relation between GDP per capita and health expenditure per capita across the OECD countries which consists in an overall tendency for countries with higher GDP to spend a greater proportion of it on health.³⁸

In absolute terms, the gap between the countries is much higher. Whereas Germany and Sweden spent US\$ PPP³⁹ 2,996 and US\$ PPP 2,703 per capita in 2003 respectively on health care, Greece and Spain only spend US\$ PPP 2,011 and US\$ PPP 1,835 respectively. Hungary

³⁶ EFPIA (2005)

³⁷ EU-15 ex Luxembourg plus Switzerland and Norway

³⁸ OECD (2005), "Health at a glance: OECD indicators 2005", pp 66-71

³⁹ Health Care expenditure per capita is converted to US\$ as a "common currency" to be able to compare the overall level of consumption of health goods and services across countries at a given point in time and adjusted to take account of the different purchasing power of the national currencies in each country. Therefore, the unit taken here by the OECD is US\$ PPP (purchasing power parity). (OECD (2005), p 66)

and Poland, with even lower purchasing power parity, do not even spend half of the amounts of Sweden and Germany with US\$ PPP 1,269 and US\$ PPP 744 respectively.⁴⁰

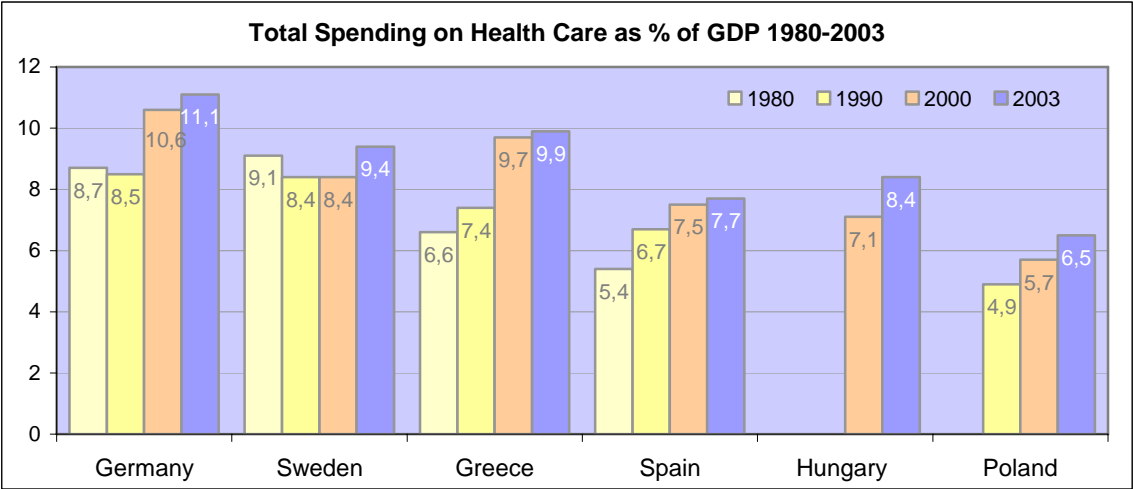


Figure 4: Total spending on health care as % of GDP at market prices 1980-2003
Source: OECD Health Data 2005

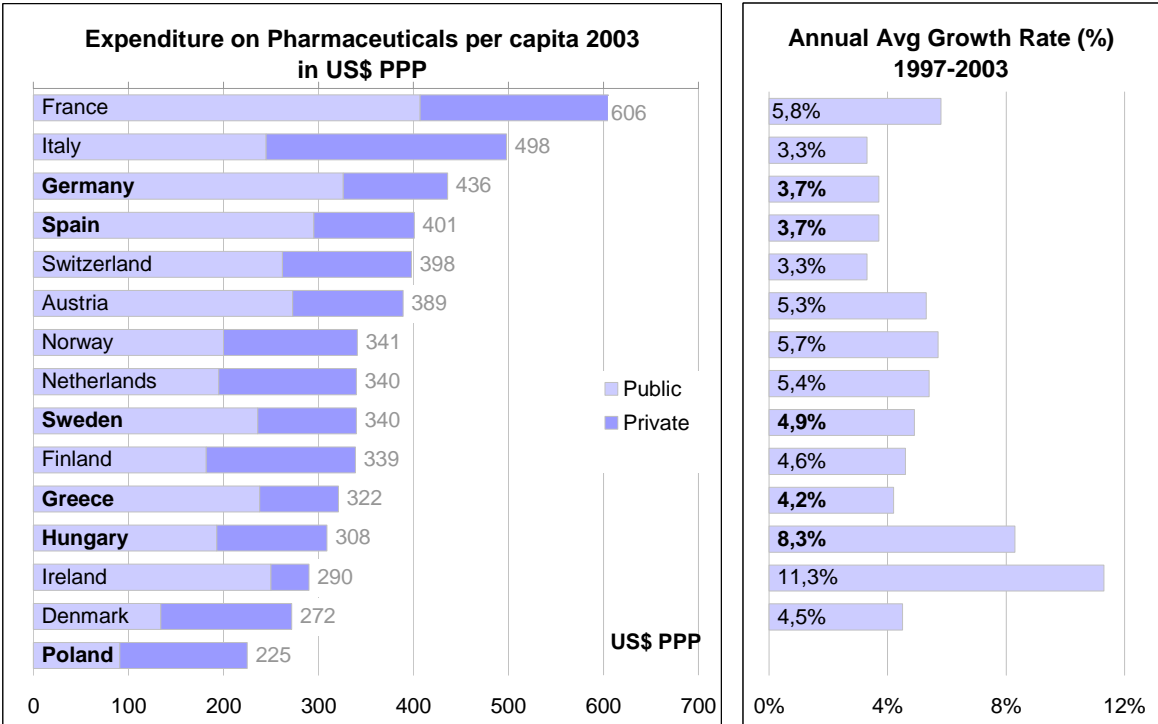


Figure 5: Expenditure on Pharmaceuticals per capita 2003 in US\$ PPP and Annual Average Growth Rate (%) on Pharmaceuticals 1997-2003
Source: OECD Health Data 2005

⁴⁰ OECD (2005), pp 66-71

The payment for pharmaceuticals by Statutory Health Insurances (SHI) and the National Health Services (NHS)⁴¹ amounted to € 24,196 million in Germany, € 1,873 million in Sweden, €8.841 million in Spain and to €1,798 in Greece. The majority of total expenditure in pharmaceuticals is generally borne by public funds and is very similar in Germany, Greece and Spain with ca. 75%, slightly lower in Sweden (70%) and Hungary (63%) and considerably lower in Poland (41%) where most of pharmaceuticals are financed privately (see *Figure 5*). The shares of pharmaceutical expenditure among payers reflects who is most interested in cost containment. If the end consumer only bears a minor part or fixed co-payment, he is not much interested in cheaper drugs as it has no great impact on him. Therefore, the more a payer's share in expenses, the higher is his incentive for product substitution by generics or parallel imports.

Similar to total expenditure on health care, pharmaceutical expenditure differs widely across countries. With US\$ PPP 436, Germany almost spent more than double on pharmaceuticals per capita than Poland (US\$ PPP 225). However, the situation of the share of pharmaceutical spending in terms of total health expenditure is exactly the opposite. Whereas in Poland and Hungary, pharmaceutical spending constitutes with 30.3% and 27.6% respectively almost a third of total health expenditure, it is only ca. 15% in Germany, Sweden and Greece.⁴² All OECD countries experienced a significant annual growth of 3.7% on average in Germany and Spain, 4.9% in Sweden, 4.2% in Greece and 8.3% in Hungary.

Pharmaceutical spending constitutes a growing part of health expenditure across OECD countries and results in particular from the introduction and diffusion of new and more expensive drugs. This rising expenditure in the short term is, however, expected to lead to savings in the long term. In real terms, per capita spending on drugs has risen by more than a third on average since 1997 in the OECD countries and has been an important driver in the overall increase in total health care expenditure. A significant factor affecting pharmaceutical and health care spending are the differences in income levels across countries.⁴³

⁴¹ only ambulatory care

⁴² Pharmaceutical spending as a percentage of total health expenditure 2003: Germany: 14,6%, Sweden: 12,6%, Greece: 16%, Spain: 21,8% (OECD (2005))

⁴³ OECD (2005), pp 74-75

3.4 Generic Products

The share of generic products (i.e. products with the same active ingredients as the original product that are marketed when the IP right protection is exhausted) is generally significantly lower in price-controlled environments than in non-price controlled ones. During the past 12 years, Germany has evolved into one of the world's most generics-friendly country. With generic sales amounting to 26.8% of its domestic total pharmaceutical market, it takes the first place in Europe, followed by Denmark and the Netherlands.⁴⁴ On average, 76% of all SHI prescriptions and 68% of sales in the generics-eligible market in Germany were generated by imitation products in 2003.⁴⁵ An increase in generic sales signifies also a decrease in sales of original products as generics are prescribed as substitutes after the patent protection period is over. Since their prices are in general significantly lower than those of original products, they accrue to important savings in pharmaceutical spending. Generic substitution is often required by law (see Chapter 4). For example, substitution by cheaper products refers equally to parallel import products and generics.

This illustrates that generics and parallel import products can be seen as substitutes since they both provide a less expensive alternative to locally sourced originals. Cost containment in the health care sector is an objective pursued in all countries across Europe though by different measures. Low parallel import rates in Germany but high sales of generics opposed to high parallel import rates in Sweden but moderate sales of generics suggest a negative correlation between these two variables.

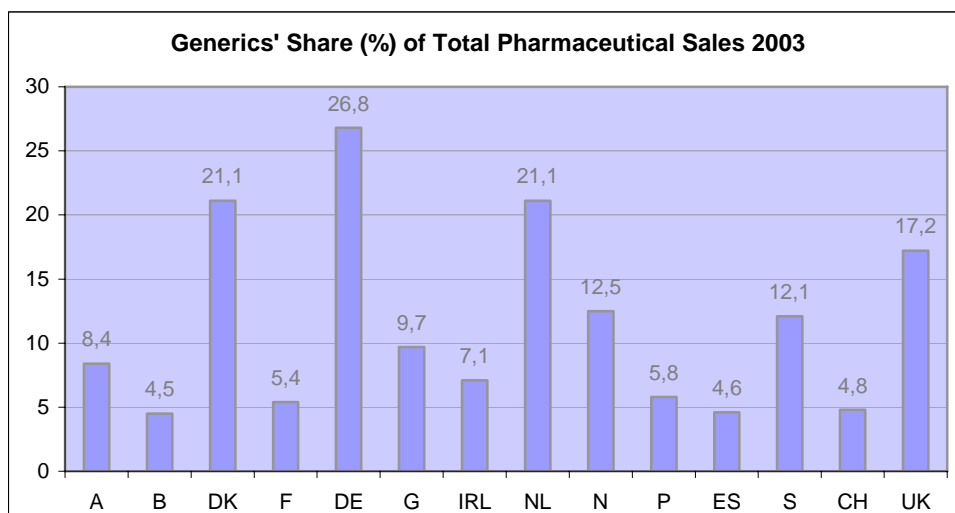


Figure 6: Generics' share (%) of total pharmaceutical sales 2003
Source: EFPIA 2005

⁴⁴ EFPIA (2005)

⁴⁵ VFA (2005)

3.5 Price Structures and Comparison

A comparison of average European pharmaceutical prices (*Figure 7*) at wholesaler level reveals a basic division of Europe into North and South with the exception of Portugal and Norway. In the Northern half, Switzerland has by far the highest prices at an index level of 124, followed by UK and Ireland with 112. Germany ranges in the middle with 100 whereas Sweden is located at the lower half of the Northern countries with an index of 95. Greece has by far the lowest price level with 82 points, Spain is located at a level of 86 points. This indicates that in terms of average prices, Sweden is not a classical high price country. This differs though if specific products prices are compared individually.

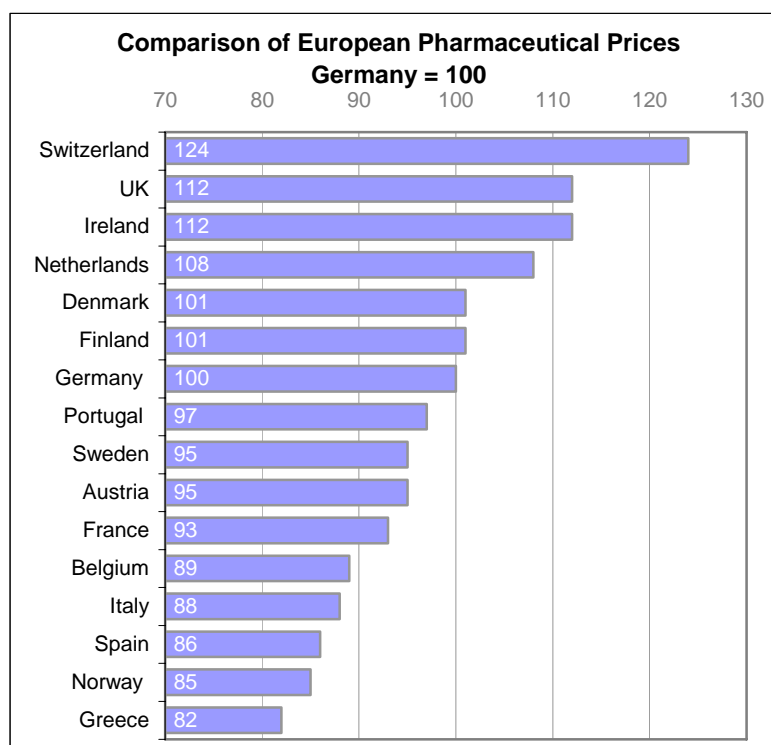


Figure 7: Comparison of European Pharmaceutical Prices based on Wholesaler's prices as of March 2004
Source: LMI, VFA 2005

However, these indices have to be seen in relation to the price structure in the countries (see *Figure 8*). In addition to the wholesaler's price level, pharmacies' margins and taxes have to be added. On European average, the manufacturer receives 62.22% of the pharmacy's sales price, the wholesaler 6.12%, and the pharmacy 22.54%. The residual 9,12% are taxes.⁴⁶

The proportions vary highly between countries. The pharmacies' margin can differ between 16% and 29% of the sales price, whereas taxes constitute a proportion between 0% and 21% of the end price. The VAT rates for pharmaceutical products vary not only between countries

⁴⁶ BPI (2005), "Pharma-Daten 2005", p 29.

but also according to the classification of the product (depending on whether the drug is OTC, prescribed and/or reimbursed).

Whereas in Sweden, for example, prescribed drugs are excluded from VAT compared to OTC products which are subject to 25% VAT, all products sold in Germany are subject to the VAT standard rate of 16% (see Table 4). Hence, the wholesalers' price makes up between only 59% (Germany) and 84% (Sweden) of the end price.

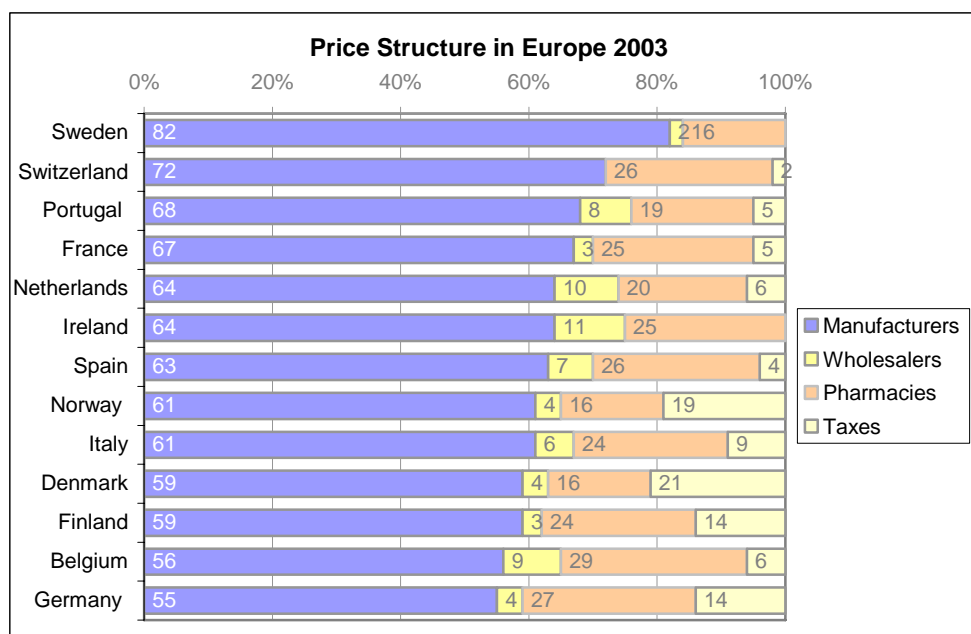


Figure 8: Price Structure in Europe 2003

Source: VFA 2005. (S, F, NL, I: only prescribed or reimbursed pharmaceuticals)

	VAT Standard Rate	VAT for prescribed pharmaceuticals	VAT for OTC products
Austria*	20.0	20.0	20.0
Belgium	21.0	6.0	6.0
Denmark	25.0	25.0	25.0
Finland	22.0	8.0	8.0
France**	29.6	2.1-5.5	2.1-5.5
Germany	16.0	16.0	16.0
Greece	18.0	8.0	8.0
Ireland	21.0	0.0-21.0	0.0-21.0
Italy	20.0	10.0	10.0
Netherlands	19.0	6.0	6.0
Norway	25.0	25.0	25.0
Portugal	19.0	5.0	5.0
Spain	16.0	4.0	4.0
Sweden	25.0	0.0	25.0
Switzerland	7.6	2.4	2.4
UK	17.5	0.0	17.5

Table 4: VAT Rates in Europe as of 01.01.2005

Source: EFPIA 2005

*Austria: 0% for reimbursed medicines (VAT refunded); **France: 2,1% on reimbursable medicines, non-reimbursable: 5,5%; ***Ireland: oral medication 0%, other 21%; ****UK: 17,5% on medicines purchased by hospitals.

A price comparison between the most common presentations of specific drugs shows that the price difference between low-price and high-price countries can be significant indeed (see *Table 7* and *Table 8* below, page 24). For example, the most common presentation of Zocor (simvastatin) in Germany costs €141 compared to €49 in the lowest price country for this product (2002), i.e. the product only costs 34% of the German market price. Lipitor (atorvastatin) in the most common presentation costs €103 in Sweden compared to €54 (52%) in the lowest price country.⁴⁷ In general, a difference in price does not automatically trigger parallel trade. An important determinant for its penetration is the product market size in the importing country which classifies its success along with the demand for less expensive substitutes.

3.6 Figures on Parallel Imports in Pharmaceuticals

In 2003, parallel trade in the European Union was estimated to amount to €4,265 million which represents 5% of the pharmacy market value at ex-factory prices. Shares of parallel imports as of total domestic pharmaceutical markets are expressed in *Figure 9*. With 17.1% (2003), the UK is by far the largest aim of parallel imports and has more than double the amount of parallel importation than Germany. The share of parallel imports reflects the price levels in the countries: The UK, Denmark and the Netherlands are among the five countries with the highest prices in Europe whereas Sweden and Germany range in the middle (compare *Figure 7*).

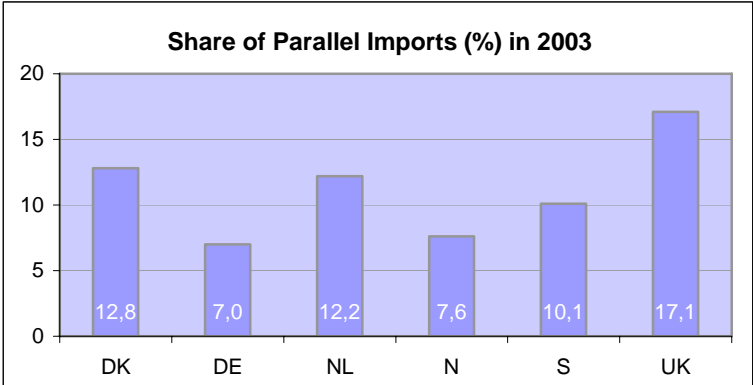


Figure 9: Share of Parallel Imports (%) in 2003 in primarily affected EU countries and Norway
 Source: EFPIA 2005 (Norway: estimate)

⁴⁷ Kanavos et al (2004), pp 197 and 200

Figure 10 shows the increase in parallel imports in Sweden and Germany from 1997 to 2005 and opposes them to the increase in parallel exports in Greece. Over five years, parallel imports have increased by five times in Sweden from 1.9% to 10.1% and by four times in Germany from 1.7% to 7.1%. Parallel exports in Greece increased more than 20 times from 0.9% to 21.6% of the total market size. Unlike the nearly constantly increasing parallel imports in Sweden to 12.2% in 2005, Germany is experienced considerable decreases from the peak in 2001 of 7.1% to 4.9% in 2004. Parallel exports in Greece have grown very strongly until 2001 but decreased in 2002.⁴⁸ The decrease of parallel imports in Germany is mainly due to lacking incentives. The major decrease in 2004 can be attributed to the amendment of § 129 I SGB V (Code of Social Law V) which requires that prices of parallel imported drugs must be at least 15% cheaper than the domestic product. Furthermore, even if pharmacists are obliged to sell a certain percentage of parallel imported products, they have no incentive to do so. On the contrary, the higher market penetration in Sweden is on the one hand due to no legal minimum price differential which entails higher incentives for traders and, on the other hand, due substitution legislation which equally refers to parallel import products and generics.⁴⁹ In absolute terms, parallel import sales in Germany (Sweden) increased from €216 million (SEK 270 million) in 1998 to over €1,000 million in 2004 (SEK 2,309 million in 2002).

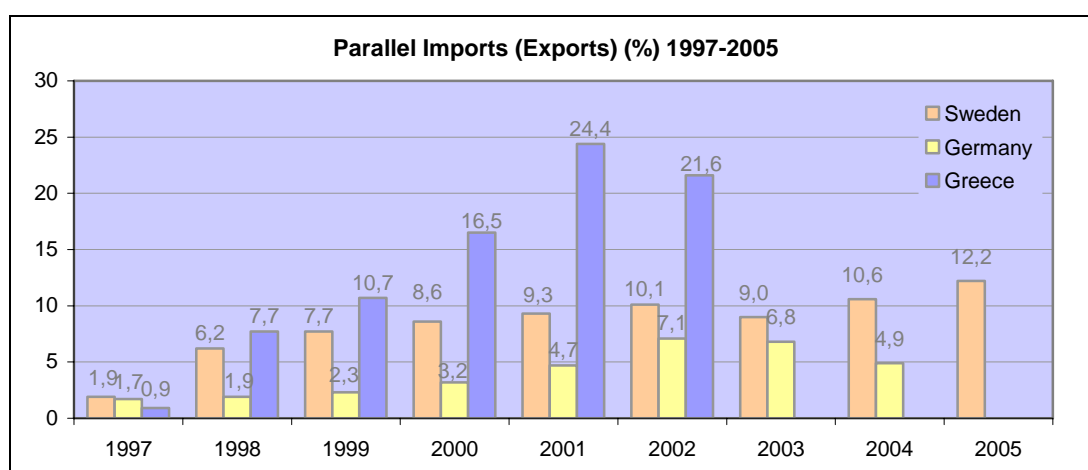


Figure 10: Share of parallel imports in Sweden and Germany opposed to parallel exports in Greece as % of the respective total pharmaceutical markets 1997-2005
Source: Kanavos et al 2004, p 14 ; VFA 2002 ; LIF 2006

⁴⁸ No numbers were available for 2003-2005.

⁴⁹ See Chapter 4.1.2 and 4.2.2 on national measures encouraging PI and Chapter 6.4 on interest and benefits of pharmacists.

Parallel trade concentrates however on high-volume products, i.e. few products with high sales and large price differences since they promise the highest margin for parallel importers. parallel imports of certain products, e.g. olanzapine and risperidone in Germany, constitute more than 60% of the total product market. Parallel imported clozapine in Sweden and losartan in the UK even have product market shares of over 70% (2002). However, for most other products, market shares of parallel imports are usually not higher than 20%.⁵⁰

Product(group)	Denmark	Germany	Netherlands	Norway	Sweden	UK
HMG CoA Reductase Inhibitors (Statins)						
Atorvastatin	5%	0%	12%	2%	17%	54%
Pravastatin	0%	1%	7%	14%	19%	38%
Simvastatin	56%	9%	51%	36%	0%	65%
Atypical Anti-Psychotics						
Clozapine	13%	0%	10%	58%	74%	0%
Olanzapine	0%	63%	8%	11%	24%	47%
Risperidone	25%	65%	33%	42%	32%	45%

Table 5: *Market shares of selected parallel import products, 2002.*
Source: Kanavos et al 2004, p 157

Product(group)	Denmark	Germany	Netherlands	Norway	Sweden	UK
HMG CoA Reductase Inhibitors (Statins)						
Atorvastatin	26%	0%	6%	6%	12%	6%
Pravastatin	0%	9%	12%	2%	6%	12%
Simvastatin	6%	5%	22%	1%	0%	22%
Atypical Anti-Psychotics						
Clozapine	6%	0%	8%	4%	17%	0%
Olanzapine	0%	6%	15%	1%	13%	0%
Risperidone	38%	10%	7%	1%	14%	0%

Table 6: *Average price spread between domestic and parallel import products (list or NHS prices in each study country), 2002*
Source: Kanavos et al 2004, p 183

The average price spread between domestic and parallel import products (list or NHS prices) varies highly between products and can amount up to 34%. However, when parallel import shares on particular product markets and the respective average price spread between domestic and parallel import products are compared, it is observable that already relatively low-price differentials of 1% to 10% suffice for a large product market share of parallel imports.

⁵⁰ Kanavos et al (2004), pp 91-92 and 157.

The average parallel importers' mark ups amount to 53% in Germany and 60% in Sweden and reflect the large price differentials of the lower priced parallel exporting countries like Greece and Spain and the countries of destination. A comparison of mark ups by parallel importers and savings to health care payers illustrates who is really profiting: In Germany (Sweden), of €2,208 (€353) billion sales of 19 high volume products (only pharmacy retails) in 2002, savings to public payers amounted to €17.7 (€3.7) million and maximum mark ups⁵¹ of parallel importers to €97.9 (€18.5) million. This means that maximum mark ups by parallel importers are 5.53 (4.89) times higher than savings to payers.⁵² A different study estimates the total savings to the SHI at €194 million in Germany and €46.7 million in Sweden. In the latter, an additional €10.1 million direct savings accrue to patients.⁵³ Benefits are considered more in depth in Chapter 6.

Table 7 and Table 8 illustrate absolute price differentials between parallel import and locally sourced, selected drugs and maximum potential mark ups for the parallel importer. It clarifies the large discrepancy between the only slightly lower parallel import sourced product compared to the locally sourced product when compared to the potential mark ups for parallel traders. Whereas parallel import sourced drugs accrue to rarely more than 12% savings in comparison to the locally sourced drug (in Germany even less), potential mark ups range in general around 50-60% and can amount to peaks of 170%.

Product(group) GERMANY, 2002, €	Price of PI drug	Price of locally sourced drug	Price Δ locally sourced - PI	Price in lowest price country	Average of the three lowest price	Maximum potential mark up
HMG CoA Reductase Inhibitors (Statins)						
Atorvastatin	N/A	N/A	N/A	N/A	N/A	N/A
Pravastatin	74.8	81.5	6.7 (8.2%)	59.1	62.7	15.1 (25.5%)
Simvastatin	135.2	141.1	5.9 (4.1%)	49.6	73.9	85.6 (172.5%)
Atypical Anti-Psychotics						
Clozapine	N/A	N/A	N/A	N/A	N/A	N/A
Olanzapine	76.6	80.9	4.3 (5.3%)	46.2	50.8	30.4 (65.6%)
Risperidone	99.5	110.8	11.3 (10.1%)	46.7	54.8	52.8 (113%)

Table 7: Price comparison of most common presentations in Germany (parallel import and locally sourced) to lowest price exporting countries and potential mark ups for selected high volume drugs
Source: Kanavos et al (2004), p 197

⁵¹ Calculations are based on the price differential between lowest pharmacy purchasing price in potential exporting countries (e.g. Spain, Greece) and domestic product prices.

⁵² Kanavos et al (2004), p 181

⁵³ YHEC (2003)

Product(group) SWEDEN, 2002, €	Price of PI drug	Price of locally sourced drug	Price Δ locally sourced - PI	Price in lowest price country	Average of the three lowest price	Maximum potential mark up
HMG CoA Reductase Inhibitors (Statins)						
Atorvastatin	91.0	103.2	12.2 (11.8%)	54.8	69.1	36.2 (66.1%)
Pravastatin	91.1	96.9	5.8 (5.9%)	69.1	77.9	22.0 (31.8%)
Simvastatin	N/A	N/A	N/A	N/A	N/A	N/A
Atypical Anti-Psychotics						
Clozapine	44.9	52.4	7.5 (14.3%)	30.1	32.7	14.8 (49.2%)
Olanzapine	272.4	311.8	39.4 (12.6%)	176.0	193.1	96.4 (54.7%)
Risperidone	272.4	311.8	39.4 (12.6%)	176.0	193.1	96.4 (54.7%)

Table 8: Price comparison of most common presentations in Sweden (parallel import and locally sourced) to lowest price exporting countries and potential mark ups for selected high volume drugs
Source: Kanavos et al (2004), p 200

3.7 Summary

Even though the European pharmaceutical industry is characterised by an annual 7.3% growth and sales of US\$ 169.5 billion, it is still in second place behind its main competitor, the US. Its significant contribution to general R&D activities and employment of more than half a million people characterise the importance of the pharmaceutical sector for economy, high technology R&D as well as social welfare.

In order to render the European high technology sector into the most dynamic and competitive of the world, which also includes the pharmaceutical sector, Europe will always struggle to catch up or out-compete its main competitor, the US. Not only are R&D investments in the latter considerably higher, but also the share of new marketed substances. To come closer to the Lisbon aim, the pharmaceutical sector needs all the investments it can possibly obtain in connection with the elimination of potentially R&D disturbing variables such as parallel trade to increase Europe's R&D friendliness. On the contrary, pressure of cost containment due to constantly rising health care and pharmaceutical expenditure across countries leads to legal measures and incitation of the sale of generics and parallel imports in some countries. The underlying reason is that the majority of drug expenditure is born by public funds who hence have the largest concern to advocate cost-containing measures. The only way to get consumers to care more about less expensive substitute products is to make them participate in costs.

A cross-country comparison of prices illustrates the large price spread and the different price structures. It also shows that parallel import is does not only concern traditional high-price countries like Germany, but also medium price countries such as Sweden. The crucial factors are individual product prices which can fluctuate considerably from the average, combined with a high sales volume that leaves space for parallel imports and makes them profitable. That price differentials are not the only reason for parallel trade is confirmed by the very different parallel import rates across countries. Legal measures and incentives for stakeholders are important influencing factors.

4 National Policies on Pricing, Reimbursement and Parallel Trade

This chapter aims at providing the reader with more detailed information on the actual price policies in combination with reimbursement measures as they influence the comportment of stakeholders considerably. Especially in recent years they were characterised by a lot of changes due to the increasing pressure of cost containment in the health care systems. Account is taken of the *general* policies as the detailed consideration of exceptions for certain patient groups is not so much relevant here and would only be confusing. Furthermore, policies on parallel trade are described to characterise the countries' attitude towards it.

4.1 Germany

As presented in Chapter 3, the German market is characterised by decreasing parallel import shares which in 2004 only amounted to 4.9%. Just in the same manner as pricing policies reflect Germany's status as a high-price country, policies on and missing incentives for parallel substitution reflect the low level of parallel imports.

4.1.1 Pricing and Reimbursement Policies

The authorisation of new drugs is operated by the Federal Institute of Drugs and Medical Products. Manufacturers are basically free to set manufacturer prices. However, the final setting of pharmacy prices for drugs only or potentially available on prescription is set according to the Pharmaceutical Price Regulation. It defines the profit margin that wholesalers and pharmacies are allowed to add on the manufacturer's price and to the wholesaler's price respectively for their services. Recommendations and guidelines for possible reimbursement of certain products are laid down in the Pharmaceutical Guidelines.⁵⁴ The Federal Association of Sickness Funds is responsible for the actual pricing of new drugs.

Following several major reforms in the health system in since the 1990s, Germany is now strongly focusing on cost containment. Although cost efficiency does not play a role at all in the licensing procedure as opposed to scientifically proven efficacy and safety, it is becoming

⁵⁴ Rychlik, R. (2005), "Erstattungsprozeduren in Europa und USA", Bundesverband der Pharmazeutischen Industrie e.V., Berlin, pp 10-11.

an important factor for reimbursement eligibility. As a basic principle, in order to qualify for reimbursement, a prescription has to be appropriate, economic (cost-efficient) and necessary. Whereas prior to 2004, basically all registered or licensed drugs could be prescribed and were therefore eligible for reimbursement in the statutory health insurance system, from 2004 on non-prescription drugs are generally excluded from reimbursement.^{55 56}

Generic substitution was introduced in August 2002. Under the *aut idem* regulation pharmacists have to substitute non-patented prescribed drugs over a certain substitution price line by cheaper products with the same active ingredients, except if the physician explicitly objects. However, no incentive measure for pharmacists to do so was implemented and practice shows that this regulation does not work out very well.⁵⁷

The definition of substitution classes in the price reference system was altered in 2004 and led to a lowering of the substitution price line, i.e. the price that is reimbursed by the SHI. If the patient insists on more expensive products, he has to bear the price difference himself in form of additional co-payments.⁵⁸ In any case, patient co-payment have to be made to the amount of to 10% of the product price, but at least €5 and not exceeding €10.^{59 60} After a preliminary ruling at the ECJ⁶¹ and the Düsseldorf Regional Court's verdict in 2004, now even new patented products can be included in substitution classes and therefore in the reference price system if no added benefit could be proven. By this measure launches of expensive me-too products shall be prevented.⁶²

Co-payments work as a disincentive on patients to insist upon the prescription of more expensive original products. As in particular original products which can be generically substituted lie above the substitution line and patients have to pay additional co-payments for them, they could potentially profit from cheaper parallel imports as the price is still reimbursed up to the substitution line and the savings can be yielded directly by the patient.

⁵⁵ Exceptions are possible in cases of particular hardship, where the doctor may prescribe particular non-prescriptive products of the Exception List.

⁵⁶ Busse, R., Schreyögg, J. and Henke, K.-D (2005), "Regulation of pharmaceutical markets in Germany: improving efficiency and controlling expenditures?", *International Journal of Health Planning and Management*, Vol. 20, p 332.; Rychlik (2005), pp 10-11.

⁵⁷ Busse et al (2005), pp 338-339

⁵⁸ Bundesministerium für Gesundheit (BMG) (2006a), "Die Arzneimittel-Festbeträge – Grundsätzliche Informationen", available online at http://www.bmg.bund.de/cln_040/nn_605028/DE/Themenschwerpunkte/Gesundheit/Arzneimittel/Die-Arzneimittel-Festbeträge-1940.html, accessed 03/03/2006

⁵⁹ The annual co-payments of a patient may not exceed 2% of his gross annual income (1% for patient with chronic diseases).

⁶⁰ Busse et al (2005), p 339; Rychlik (2005), p 11

⁶¹ Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01 *AOK Bundesverband and Others v Ichthyol-Gesellschaft Cordes, Hermani & Co., Mundipharma GmbH, Gödecke GmbH, Intersan, Institut für pharmazeutische und klinische Forschung GmbH* [2004] OJ C 094

⁶² Busse et al (2004), p 346

4.1.2 Institutional Policies Encouraging Parallel Imports

German pharmacists are both legally and contractually bound to dispense parallel imports. § 129 I of the Social Code Book V obliges them to “issue a more favourably-priced imported medical product according to the requirements of the framework agreement”. A contractual agreement between the association of sickness funds and the national association of pharmacists determines the dispersion of parallel imports if certain price conditions are fulfilled. Until 2004, the parallel imported product had to be at least 10% or €0,51 cheaper than the non parallel import alternative which led to a continuous price convergence of parallel import and locally sourced drugs. Consequently, from 2004 on the differential has to be to at least 15% (drug price below € 100) or € 15 (drugs price over € 100) in order to attribute more of the benefit to the SHI.⁶³ In reaction, parallel imports in Germany have been decreasing from 6.8% in 2003 to 4.9% in 2004 since the higher the required price differential is, the lower the profit and therefore the incentive for parallel traders. All savings accrue to statutory sickness funds except if the product is excluded from reimbursement or substitution price lines are activated, then the patient will benefit directly as his direct expenses in terms of the full product price or co-payments are reduced. On the contrary, there is no cash benefit for the pharmacists who hence has no incentive to dispense parallel import drugs.⁶⁴

However, the Pharmaceutical Expenditure Limitation Act obliged pharmacists to generate at least 5.5% in 2002 and 7% in 2003 respectively of their turnover from officially listed parallel imports. This quote is not product related and describes simply the proportion of parallel import products and non parallel import products. If the pharmacist does not achieve this quota in a given month, the pharmacy’s reimbursement bill is reduced for that month. On the other hand, if quota is exceeded, the pharmacy receives a credit which can be offset against months where the quota was not fulfilled.⁶⁵ The quota system works as a disincentive (penalty) for pharmacists for not dispensing parallel import pharmaceuticals, but only as an incentive to fulfil the obligation, i.e. not as an incentive to disperse more parallel imports than required. This is reflected in the relatively low quota of parallel imports in Germany: 7% are required by law and are not even attained by the actual quota which amounts to 4.9% (2004). Savings from parallel trade substitution have not yet been possible to measure, but both the

⁶³ VFA (2004), “Reimporte: Kostendämpfung auf dem Irrweg”, available online at <http://www.vfa.de/de/wirtschaft/artikelwi/reimporte.html>, accessed on 21/04/2006

⁶⁴ Kanavos et al (2004), pp 69-70

⁶⁵ Ibid, p 63

legislator and sickness funds expect major savings from this measure.⁶⁶ Yet incentives for pharmacists who are the major potential distributor are low.

To further reduce expenditure of statutory sickness funds, since January 1st, 2003 manufacturers are obliged to grant them a 6% discount.^{67 68} This discount does not apply for pharmaceuticals that are subject to a substitution price line but does apply to locally sourced and parallel import products likewise.⁶⁹

Since physicians determine pharmaceutical expenditure significantly by their prescription behaviour, the government also experimented in its reforms with various measures to control this behaviour, both on national and on a decentralised regional level. With the second Restructuring Act in 1997, practice-specific targets according to different groups of specialists were introduced. If overspending of budgets exceeded 125% which physicians could not justify sufficiently, a certain proportion had to be paid back. Physicians' associations supplemented this target for individual physicians according to their medical speciality and included a requirement for certain proportions of generics and parallel imports.⁷⁰ The decentralisation did however not work out in practice though it constitutes in general an important incentive for the substitution by cheaper drugs such as generics and parallel imports. The new Law on the Improvement of Efficiency in Drug Supply which entered into force on May 1st, 2006 tries another approach by calling physicians more to account for their prescriptions through a so-called bonus malus regulation. The price worthiness of drugs shall be classified in medication groups per defined daily dose on a national level but can be replaced by contractual agreements on Länder level. Furthermore, hospitals shall pay attention to efficiency of dismissal medication.⁷¹ Though these measures do not directly relate to parallel imports, they influence them in terms of incentives for physicians to fulfil their cost containment obligation.

⁶⁶ Busse et al (2005), p 340

⁶⁷ The mandatory discount amounted to 16% in 2004, but was lowered to 6% again in 2005.

⁶⁸ Rychlik (2005), pp 10-11

⁶⁹ Personal communication with Monica Dahl of the BMG (Federal Ministry of Health), 25/04/06

⁷⁰ Busse et al (2005), p 343-344

⁷¹ BMG (2006b), Press Release "Gesetz zur Verbesserung der Wirtschaftlichkeit in der Arzneimittelversorgung (AVWG) tritt zum 1. Mai 2006 in Kraft", online at http://www.bmg.bund.de/cln_040/nn_600110/DE/Presse/Pressemitteilungen/Presse-2-2006/pm-28-4-06.html, accessed 02/05/2006

4.2 Sweden

The comparison of average drug prices places Sweden in the middle of European countries. Opposed to Germany, parallel importation levels are considerably higher with 12.2% in 2005 and constantly increasing. This can mainly be attributed to two factors: Not only is Apoteket, the Swedish pharmacy, a state monopoly but is also granted ex-post lump sum payments for its work with parallel imports and generic substitutions. Moreover, the responsibility for drug expenditure is allocated at the county councils, i.e. at decentralised level, and hence provides a stronger incentive for cost control than the centralised German system.

4.2.1 Pricing and Reimbursement Policies

The Swedish pharmaceutical pricing system is in general rather flexible with low constraints for pharmaceutical companies who are *de jure* free to price their products. However, this freedom is in practice limited since, if the product shall qualify for reimbursement, the price is set by the Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden, LFN) which was introduced on October 1st, 2002. The main objective of the Swedish pharmaceutical system is rational drug utilisation: As cost-effectiveness is now the major determinant in price setting,⁷² pharmaceutical companies are required to submit economic evaluations of their product if it shall qualify for reimbursement. Cost-effectiveness is thereby not assessed in connection with medical indications but within product groups.⁷³

Price negotiations can be held parallel to the licensing procedure and are therefore rather fast: Decisions have to be made within 90 days, but on average only take six to eight weeks. The manufacturer may propose price alterations at a later stage which are also subject to approval by the LFN. A price decision concerns both the pharmacy's purchasing and selling price. This automatically also implies the determination of the pharmacy's margin.⁷⁴

The price referencing system was abandoned in 2002 and generic substitution introduced instead. As in Germany, the pharmacist shall substitute the prescribed product by a less expensive product except if the physician explicitly precluded this option.⁷⁵ If the patient

⁷² Act (2002:160) on pharmaceutical benefits, Section 15, available online at http://www.lfn.se/upload/English/ENG_Act_2002-160.pdf, accessed 04/03/2006

⁷³ Anell, A. and Persson, U. (2005), "Reimbursement and clinical guidance for pharmaceuticals in Sweden", *European Journal of Health Economics*, Vol. 50, p 276

⁷⁴ Lindquist, J. (2002), "Pricing and Reimbursement of Drugs in Sweden", *European Journal of Health Economics*, Vol. 3, No. 2, p 68

⁷⁵ Act (2002:160) on pharmaceutical benefits, Section 21

insists on a more expensive original, he has to make an out-of-pocket payment for the price differential. The current reimbursement system contains five reimbursement categories. For annual individual expenditure below SEK 900, the patient bears all costs, between SEK 900 and SEK 1,700, 50% are reimbursed, thereafter 75% up to SEK 3,300, 90% up to SEK 4,300 and costs over this sum are fully reimbursed.⁷⁶ Maximal annual costs on prescription drugs for the patient amount therefore to SEK 1,800. Whereas prior to the introduction of the current system, some drugs were entirely free of charge for patients, nowadays insulin is the only drug that is completely free of charge. The average patient's co-payments varied between 21% and 28% in the years 1997-2001.⁷⁷

4.2.2 Institutional Policies Encouraging Parallel Imports

Unlike in Germany, there is no explicit policy in place that encourages the dispersion of parallel import drugs in Sweden. Yet, drug budgets are allocated at the 21 county councils who are not only responsible that they are not exceeded, but have to pay for any overspending themselves out of their own budget destined for other purposes. They hence have a strong incentive to meet budget restrictions and favour less expensive drugs such as parallel imports. These are also indirectly favoured in comparison to original drugs as the institutional substitution policy refers in general to "less expensive, substitutable drugs"⁷⁸ and hence includes both generics and parallel import products by which the pharmacist shall substitute the more expensive prescribed original. The pharmacist has the duty to inform the patient about the substitution.

Furthermore, the LFN makes one-off payments to Apoteket at year-end to compensate them for their work with generics and parallel import drugs in form of increasing their retail margin. In 2002, Apoteket received SEK 50 Million extra for their additional work with generics and parallel trade as a retrospective one-off bonus payment. This hence works as an incentive for Apoteket to increase their work with parallel importation. County councils themselves and the state benefit from parallel import substitution as well as they both pay for shares in increases or decreases in the drug bill.⁷⁹

The Swedish drug regulatory authority decreased the fee for parallel import applications in 2000 to SEK 15,000 compared to SEK 200,000-340,000 for a new product. The annual fee

⁷⁶ Act (2002:160) on pharmaceutical benefits, Section 5

⁷⁷ Lindquist (2002), p 68

⁷⁸ Act (2002: 160) on pharmaceutical benefits, Section 21, first sentence

⁷⁹ Kanavos et al (2004), pp 65 and 71

for parallel imports was also decreased, both working as an indirect incentive to encourage parallel imports. In general, parallel import products can be freely priced as long as their prices are lower than those of the original products.⁸⁰ In contrast to Germany, no policy requiring minimum price differentials between parallel imports and locally sourced products is in place.

4.3 Spain

The status as low-price countries of both Spain and Greece can be partly explained by their external referencing to other low-price countries in pricing which then forms a circle. Reimbursement measures are considered only very briefly as the important characteristic for parallel imports are prices and export measures.

4.3.1 Pricing and Reimbursement Policies

Pricing and reimbursement decisions are operated by the General Directorate for Drugs and Health Care Products. Drug price regulation is divided into three components which include definition of the manufacturer's price at market entry and any posterior increase, the wholesaler's gross margin, and the pharmacist's gross margin. Pricing of new products is done by taking these three components into account and by external referencing to low-price countries such as Italy, Greece, France and Portugal if the product is already marketed there, as well as the product price in the country of origin.⁸¹ Price increases have to be explicitly authorised. The margin of industrial profit allowed in manufacturer's price amounts to 12-18%, whereas the pharmacists' and wholesalers' margins are fixed at 27.9% and 6.92% respectively, but not exceeding € 33,54 and € 8,32 respectively.⁸² Pricing decisions take usually two to three months.⁸³

Manufacturers have to apply for public reimbursement. Important factors in the reimbursement decision are the availability of already existing drugs and of similar or better

⁸⁰ Kanavos et al (2004), p 77

⁸¹ Kanavos, P. (2005), "Regulating Pharmaceutical Prices", Presentation at the Medical University of Vienna, July 5, 2005, slide 20; available online at www.meduniwien.ac.at/files/25/8/kanavos-regpricing.5_july_2005.ppt, accessed 06/03/2006

⁸² Real Decreto-Ley 5/2000, de 23 de junio, de Medidas Urgentes de Contención del Gasto Farmacéutico Público de Racionalización del Uso de los Medicamentos

⁸³ Rovira, J. and Darbá, J. (2001), "Pharmaceutical Pricing and reimbursement in Spain", *Health Economics in Prevention and Care*, Vol. 2, No. 2, p 40

alternative treatments for the same disease that are available at lower prices.⁸⁴ Generic substitution was introduced in 2000 and entailed increasing pressure on drug prices (also on originals) due to its clear privilege by the government (e.g. by considerably higher margins for pharmacists on the sales of generics) in order to save on health care expenditure. Companies registering a generic product must launch it within two months of its authorisation to prevent delayed market entries.⁸⁵ The price differential between original and generic products increased to 35% in 2004.⁸⁶

4.3.2 Policies on Parallel Trade

Spain as one of the largest parallel exporters has become uncomfortable with its status and tried to implement certain measures to improve transparency over what is distributed domestically and what is exported. A dual pricing decree with higher prices for export products was proposed in May 2003 but withdrawn after few weeks which is not surprising after the still pending judgment in *GlaxoWellcome v Commission*⁸⁷. A decree requiring wholesalers to register and report the destination of their products was introduced in June 2003, emphasising parallel exports. However, enforcement and compliance by wholesalers is basically unknown. Attempts are made establishing a database that aggregates data on parallel exports; however, it is unknown when this will become operational and/or accessible and how these export monitoring measures have to be treated with regard to Art. 28-30.⁸⁸

4.4 Greece

4.4.1 Pricing and Reimbursement Policies

Both prices of OTC products and prescription drugs are subject to control of an entity of the Ministry of Development which consists of various representatives of the pharmaceutical industry, sickness funds and other ministries. The pricing procedure takes usually 90 days and varies depending on whether the product is imported or domestically produced.⁸⁹ For imported drugs which dominate the market (57% market share in terms of sales in 2000)⁹⁰ the

⁸⁴ Ley General del Medicamento, Art. 94; Rovira and Darbá (2001), p 41

⁸⁵ Rovira and Darbá (2001), pp 41-42

⁸⁶ Rychlik (2005), p 45

⁸⁷ Case T-168/01 Glaxo Wellcome v Commission (pending)

⁸⁸ Kanavos et al (2004), pp 76-77

⁸⁹ Rychlik (2005), p 19

⁹⁰ Kontozamanis, V., Mantzouneas, E. and Stoforos, C. (2003), "An Overview of the Greek Pharmaceutical Market", European Journal of Health Economics, Vol. 4, No. 4, p 328

de facto lowest European ex-factory price is applied. The product in question has to be already marketed in at least two other European countries whereby the lowest price is relevant. For domestically produced or packaged products the lowest ex-factory price in Europe is the upper limit: if cost factors determine the price at a level superior to the taken benchmark price, the price is reduced to the latter's lower level.⁹¹ Generic prices should be at least 20% below the original product's price. According to a decision of the Supreme Court in 2001, the pricing policy is unconstitutional. However, new policies are not yet been delivered.⁹²

The Positive List for reimbursement contains mainly generic products. All included drugs have to be reimbursable in at least three of the following countries: France, Germany, Sweden, Switzerland, the UK, and the US. Sickness funds usually bear 75% of medication costs. Generic substitution is not allowed.⁹³

4.4.2 Policies on Parallel Trade

Greece is the most aggressive parallel exporting country with 22% of parallel exports in the retail market. The Greek High Court ruled that there shall be more countries considered than the lowest-price countries when determining pharmaceutical prices. However, little has changed since the publication of the ruling. Similar to Spain, the National Drug Organisation has issued two circulars in 2001, one which obliges firms to report on a confidential basis the quantities they export and another which obliges companies to cover local needs plus a 25% safety minimum. The latter was a reaction to drug shortages that occurred in different parts of the country and were attributed to parallel export activity. According to the 'public service obligation' laid down in Directive 2001/83⁹⁴, Art. 1(18), wholesalers are obliged to guarantee permanently an adequate range of medical products to meet the demand of a specific geographic area and to deliver the supply within a very short period of time. Whereas the assurance of sufficient local supply reflects this measure, there is little information on how the ECJ and the Commission perceive the monitoring of exports in relation to Art. 28-30 EC on the free movement of goods. Also, little is known about whether exporters comply with these requirements.⁹⁵

⁹¹ Koutzamanis et al (2003), p 329

⁹² Rychlik (2005), p 19

⁹³ Ibid, p 20

⁹⁴ Council Directive 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67

⁹⁵ Kanavos et al (2004), pp 74-75

5 European Community Law and Parallel Imports

Parallel trade falls under two main set of rules of Community Law, i.e. rules on the internal market, particularly the free movement of goods, and competition rules. As parallel trade is mainly preoccupied with patent protected products, IP rights play a major role in assessing the legal nature of parallel imports and therefore have to be considered in connection with the Internal Market provisions. This chapter aims to give an overview of the legal nature of parallel trade and of which practices are allowed or not to be employed by pharmaceutical companies in order to hinder parallel imports. Furthermore, a short overview of market authorisation procedures is provided.

5.1 Free Movement of Goods and Intellectual Property Rights

From an economic point of view, IP rights are twofold: Considered *ex-post*, they are anti-competitive in nature as they restrain other actors from benefiting from the innovation without the consent of the holder. Hence, they constitute barriers to entry. On the contrary, considered *ex-ante*, IP rights incite and encourage investment in innovation and lead to increased competition. Inventions can be easily copied once they are available (via reverse engineering) and without protection, innovators would be discouraged from investing.⁹⁶

From a legal point of view, it is important to consider IP rights in the light of Community Law provisions of free movement as they fall within the scope of measures equivalent to quantitative restrictions (MEQR) on trade (Art. 28 EC⁹⁷). Since IP rights are conferred on a national basis, their national (territorial) limitation conflicts with the concept of a common market. Though they could be exempted under Art. 30, the jurisprudence of the ECJ has “instead [pursued] a market-integrationist ethos at the expense of the value of IP rights.”⁹⁸

Whereas in the light of Art. 28, IP rights are considered as MEQRs and therefore obstacles to the intra-Community trade, property rights are protected in the Treaty by Art. 295:

“This Treaty shall in no way prejudice the rules in Member States governing the system of property ownership.”

⁹⁶ Korah, V. (2004), “EC Competition Law and Practice”, 8th edition, Hart Publishing, Oxford, p 291

⁹⁷ All following citations of Articles in this Chapter refer to the Treaty of the European Community without further indication.

⁹⁸ Micklitz, H. and Weatherhill, St. (1997), “European Economic Law”, Dartmouth Publishers, Aldershot, pp 303-304

However, the Court clarified in *Centrafarm v Sterling*⁹⁹,

“7. [...] whilst the Treaty does not affect the *existence* of rights recognized by the legislation of a Member State in matters of industrial and commercial property, yet the *exercise* of these rights may nevertheless, depending on the circumstances, be affected by the prohibitions in the Treaty.”¹⁰⁰

It thereby gives the provisions on free movement with regard to IP rights clear precedence over the property protection provision.

5.1.1 Overview of the Free movement of Goods: Treaty Principles and Case Law

One of the central purposes of the Treaty of Rome in 1957 was to create a Common Market which is laid down in Art. 2 EC, stating the aim of the Treaty. The central means was to establish an internal market¹⁰¹ characterised by the four freedoms of goods, persons, service and capital (Art. 3(1)(c)), to develop common commercial policy (Art. 3(1)(b)) and to ensure a functioning competition policy (Art. 3(1)(g)). The Internal Market is defined in Art. 14(2) as

“an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaty.”

The free movement of goods is commonly acknowledged as the most fundamental principle and corner stone of Community Law. Whereas Art. 3(1)(a) refers to the most obvious obstacle to the free movement of goods and regulates the prohibition of customs duties, Art. 28 targets non-tariff barriers on imports:

“Quantitative restrictions on imports and *all measures having equivalent effect* shall be prohibited between Member States.” (emphasis added)

Prohibitions or restrictions can only be exempted if they are justified on the grounds of Art. 30 which include explicitly the protection of industrial and commercial property. Exemption can only be granted as long as they are not discriminatory or means of disguised restriction:

“[T]hey shall not, however, constitute means of arbitrary discrimination or a disguised restriction on trade between Member States.” (Art. 29, second sentence).

The free movement principle of Art. 28 applies to all kinds of imports, be it direct or indirect imports, re-imports, imports of raw material or parallel imports.

The concept of MEQR includes not merely overtly protective measures which apply to imports or exports but not to domestic products (“distinctly applicable” measures), but also to

⁹⁹ Case 15/74 *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.* [1974] ECR 1147

¹⁰⁰ *ibid.*, at para 7, emphasis added

¹⁰¹ This term was introduced by the Single European Act in 1987.

those that apply equally to domestic and imported (exported) products, i.e. “indistinctly applicable” measures.¹⁰² In *Dassonville*¹⁰³, the ECJ defines MEQRs as follows:

“5 . All trading rules enacted by member states which are capable of hindering, directly or indirectly, actually or potentially, intra-community trade are to be considered as measures having an effect equivalent to quantitative restrictions.”¹⁰⁴

This definition is very broad in scope as it targets not only measures that are actually restricting but also those which have the intention or the potential to restrict trade between Member States.

In its judgment in *Cassis de Dijon*¹⁰⁵, the Court established that indistinctly measures which are necessary in order to protect mandatory requirements will not be in breach of Art. 28 or 29. Distinctly applicable measures will usually be in breach of Art. 28 or 29 and may only be justified under Art. 30. Mandatory requirements add largely to possible exemptions as they are not only wider in scope but also, on the contrary to the grounds listed in Art. 30, non-exhaustive. However, courts have to apply the principle of proportionality as restrictive measures can only be justified if they are necessary and no other less restrictive measures exist.

The extremely wide definition of the *Dassonville* formula led to a tendency of a lax, “mechanical” application, and to the justification of measures which might affect the volume of imports overall but with little actual potential to hinder imports. Therefore, in *Keck and Mithouard*¹⁰⁶, the Court saw the necessity to narrow the formula down in order to limit the prohibition to more classical trade regulation measures and exclude certain selling arrangements, even if it was only 19 years later.

In markets that fall under the subsidiarity principle of Art. 5 such as the health care sector and pharmaceuticals, the reluctance of certain market actors who traditionally benefited from specific legislative measures such as pharmacists to acknowledge the implications of the Internal Market are reflected in *Deutscher Apothekerverband v DocMorris*¹⁰⁷. Doc Morris, a Dutch pharmacy, offered internet sales of both prescription and non-prescription drugs which had been authorised either in the Netherlands or in Germany, also to customers in Germany.

¹⁰² The distinction between distinctly and indistinctly applicable measures was introduced in Directive 70/50 passed by the Commission under the then Art. 33 (7) (which has been deleted by the Treaty of Amsterdam), but is still used as a guidance on the interpretation of Art. 28 and 29.

¹⁰³ Case 8/74 Procureur du Roi v Dassonville [1974] ECR 837

¹⁰⁴ *ibid.*, at para 5; emphasis added.

¹⁰⁵ Case 120/78 Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon) [1979] ECR 649

¹⁰⁶ Joined Cases C-267&268/91 Keck and Mithouard [1993] ECR I-6097

¹⁰⁷ Case C-322/01 Deutscher Apothekerverband e.V. v 0800 DocMorris NV and Jacques Waterval [2003] ECR I-14887

The Apothekerverband (German Association of Pharmacists) challenged its operations because they were contrary to the Arzneimittelgesetz (AMG, German law on medical products) which reserved the sale of medical products exclusively to German pharmacies. Referred to in a preliminary ruling, the ECJ clarified that the AMG constituted a MEQR which violated the free movement of goods with regard to non-prescription drugs. It was only justified for prescription drugs under Art. 30 due to the risk attached to medical products and the increased risk of abuse or wrong application if the labelling was in another language. This also illustrates that market harmonisation does not stop entirely at markets that are still mostly subject to national regulation.

5.1.2 IP Rights: Specific Subject Matter, Exhaustion and Monopoly Profit

The jurisprudence of the Court not only established the principle of national exhaustion of IP rights, but in relation to this also defined the “specific subject matter” of patents and touched upon the necessity for the patent proprietor to earn a monopoly profit as a reward of his innovation investment.

The distinction between the existence and the exercise of rights was first established in *Consten and Grundig*¹⁰⁸ in connection with Art. 81 and Art. 30. The ECJ distinguished between the existence of ownership of rights under national law which Art. 295 protects and the exercise of these rights which are subject to Treaty provisions, in particular the articles on free movement of goods and competition provisions.

The same approach was taken by the Court in parallel import cases in pharmaceuticals such as *Centrafarm v Sterling* and *American Home Products*¹⁰⁹. In the former case, the patentee held patents on the product in Germany, the United Kingdom and the Netherlands, and attempted to block parallel imports from the UK into the Netherlands where price levels were much higher due to governmental repression of prices in the UK. The ECJ developed the concept of the “*specific subject matter*” of a particular kind of industrial or commercial property which may justify protection and thereby solved the dilemma of either affording priority to the

¹⁰⁸ Joined Cases 56&58/64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission* [1966] ECR 299
Consten was granted exclusive distribution rights by Grundig to sell its brand “Gint” in France and applied for regional trade mark protection to the French authorities. This enabled Consten to sue the German competitor UNEF for trade mark infringement and unfair competition which marketed parallel imports of the same product in France with German origin.

¹⁰⁹ Case 3/78 *Centrafarm BV v American Home Products Corp.* [1978] ECR 1823

protection in Art. 295 or curtailing the traditional use of IP rights by enacting supremacy of Community law.

“9. As regards patents, the specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements.”¹¹⁰

The “specific subject matter” includes both the nature of the right, i.e. to restrain others from using the invention, and the reason the law offers it, i.e. the reward for investment in innovation. The Court clarified that once patent rights have been used to obtain some rewards, they cannot be used to exclude legal imports of the product and was thereby unwilling to allow IP rights to partition the Single Market on a long-term basis:

“11. [...] a derogation from the principle of the free movement of goods is not, however, justified where the product has been put onto the market in a lawful manner, by the patentee himself or with his consent, in the Member State from which it has been imported, in particular in the case of a proprietor of parallel patents.”¹¹¹

It also touched upon a second important issue of IP rights, i.e. it accepted the necessity of the patentee to be able to reap the fruits of his innovation by earning a *monopoly profit* as a reward for his creative effort. This was, however, given little attention for some years: Later judgment relying on ground 11 took its phrasing literally and considered a patent as exhausted by any sale in another Member State by or with the consent of the holder, whether or not a monopoly profit could be earned in the country of export.

The argument put forth by Sterling that the price differences which trigger parallel imports result from Member States’ interference and not from market conditions was not dealt with by the Court. It instead referred to the Community authorities’ obligations to eliminate factors that distort competition and to harmonise national measures.¹¹² Even where measure such as price controls persist do they not justify further measures restricting the Treaty freedoms.

Later cases considered situations in which pharmaceuticals could not be patent protected in some Member States. In *Merck v Stephnar*¹¹³, Merck had marketed its drug Moduretic, which was patent protected in the Netherlands, in Italy without patent protection since the Italian patent law prohibited the grant of patents for drugs. The product was then subject to parallel

¹¹⁰ Case 15/74 *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.* [1974] ECR 1147, at para. 9

¹¹¹ *ibid.*, at para. 11

¹¹² *ibid.*, at para. 23

¹¹³ Case 187/80 *Merck & Co. Inc. v Stephnar BV and Petrus Stephanus Exler* [1981] ECR 2063

import into the Netherlands through a third party. The Court, referring to *Centrafarm v Sterling*, recognised that an exemption under Art. 30 would be justified to safeguard the specific subject matter of the patent. However, this could only be justified if the parallel imported product came from a Member State where it is manufactured and sold by a third party without the consent of the patentee. In *Merck v Stephnar*, on the contrary, the plaintiff chose himself to market the product on a non-patent protected market which would theoretically allow him a monopoly in exploiting his product and thereby the specific subject matter of the patent. The ECJ concluded that

“11. [...] if [the proprietor of the patent] decides [to market the product in a Member State where the law does not provide patent protection for the product in question] he must then accept the consequences of his choice as regards the free movement of the product within the Common Market, which is a fundamental principle forming part of the legal and economic circumstances which must be taken into account by the proprietor of the patent in determining the manner in which his exclusive right will be exercised.”¹¹⁴

13. [...] to permit an inventor [...] to invoke a patent held by him in one Member State in order to prevent the importation of the product freely marketed by him in another Member State where that product is not patentable would bring about a partitioning of the national markets which would be contrary to the aims of the Treaty.”¹¹⁵

In *Pharmon v Hoechst*¹¹⁶, the Court clarified that in order for parallel imports to be legal, the consent of the patentee to grant a license to the licensee is compulsory. In this case, Hoechst held parallel patents in, among others, the UK and the Netherlands. It was required by British law to grant a compulsory license to anyone who applied for it to the authorities. In fact, the license which prohibited exports was granted by the latter and not by the patentee himself. The licensee, ignoring the export prohibition, had produced and sold products to the Dutch pharmaceutical company Pharmon that had not been marketed on the British market first so that Hoechst did not receive any royalties for them. The judges draw a distinction between *Merck v Stephnar* where Merck had marketed his product himself without patent protection, and the current case in which Hoechst had no choice to deny a license that was in fact granted by the authorities.

“25. [...] Where, as in this instance, the competent authorities of a Member State grant a third party a compulsory licence which allows him to carry out manufacturing and marketing of operations which the patentee would normally have a right to prevent, the patentee cannot be deemed to have consented to the operation of that third party. Such a measure deprives the patent proprietor of his right to determine freely the conditions under which he markets his products.”¹¹⁷

¹¹⁴ *ibid.*, at para. 11

¹¹⁵ *ibid.*, at para. 13

¹¹⁶ Case 19/84 *Pharmon BV v Hoechst AG* [1985] ECR 2281

¹¹⁷ *ibid.*, at para. 25

5.1.3 Trade mark Protection: Re-naming and Repackaging

In contrast to its drastic view on patents, the Court has shown somewhat more moderation with regard to trade mark protection. Whereas its attitude to patents considers restrictively the essential functions they serve and only protects the possibility of the first marketing of the product in question by the manufacturer, its attitude towards trade mark protection goes further. In *Hoffmann-La Roche v Centrafarm*¹¹⁸, it defined the specific subject matter of trade mark rights as the protection of the holder against competitors who would abuse the reputation protected by the mark. Its essential function is to guarantee the consumer the original identity of the product, so as to avoid confusion or misleading.¹¹⁹

Consumer protection has, however, only been established in *Hag II*¹²⁰, where the Court reversed its judgment in *Hag I*¹²¹ and, instead of emphasising the smooth functioning of the Common Market, accepted Advocate General Jacobs' opinion on the prioritisation of consumer protection:

“[...] the function of a trade mark is to signify to the consumer that all goods sold under that mark have been produced by, or under control of, the same person and will, in all probability be of uniform quality [...] Once the owner is deprived of his exclusive right to its use, he loses the power to influence the goodwill associated with it and loses the incentive to produce high-quality goods. *Looking at matters from the consumer's point of view, the result of all this is thoroughly unsatisfactory because the trade mark no longer acts as a guarantee of origin. At the best he is confused; at the worst he is misled.* In the circumstances, it is difficult not to conclude that the essential function of the mark is compromised, its specific subject-matter is affected and – most seriously of all – its very existence is jeopardized.”¹²²

In *American Home Products*, the core question that arose concerned how far trade mark rights could be used as a means to stop parallel imports. In *de Peijper*¹²³, the Court reprimanded the Dutch government for making it difficult for the parallel importer Centrafarm to access the market due to favourable administration rules for the trade mark holder that allowed it to easily block imports. However, it did not allow a *re-naming* of the product “Serestra” which was imported from the UK to the local name “Serenid”. Its reasoning emphasised the importance of the guarantee of origin for the consumer which is of particular importance in pharmaceuticals due to their toxic nature. The manufacturer is the only one who can guarantee the origin. This has been valued more important than a facilitated marketing for the parallel importer.

¹¹⁸ Case 107/76 *Hoffmann-La Roche AG v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH* [1977] ECR 957

¹¹⁹ Korah (2004), p 303

¹²⁰ Case C-10/89 *SA CNL-Sucal NV v Hag GF AG* (“Hag II”) [1990] ECR I-3711

¹²¹ Case 192/73 *Van Zuylen Frères v Hag AG* [1974] ECR 731

¹²² *ibid.*, at para. 24 of the Opinion of the Advocate General Jacobs delivered on 13th March 1990; emphasis added

¹²³ Case 104/75 *Officier van Justitie v Adriaan Peijper* [1975] ECR 613

However, there still remains a chance of partitioning the Common Market if manufacturers use different trade marks in different countries, i.e. either through different names or, more importantly, through different package sizes. A product cannot be sold in one country if it is imported in a package size that does not exist in the country of destination as it cannot be prescribed in this form by the doctor. Different packaging could therefore constitute “a disguised restriction of trade between Member States” within the second sentence of Art. 30, if it has the *effect* of dividing the market.

This issue was treated in *Hoffmann-La Roche v Centrafarm*¹²⁴. The latter repackaged Valium from the British market into smaller packages in order to put it on the German market. The Court established guidelines as to in which circumstances repackaging is allowed, requiring four conditions to be fulfilled:¹²⁵

- (i) The use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, contributes to the artificial partitioning of markets in the Community;
- (ii) The repackaging does not adversely affect the original condition of the product;
- (iii) The proprietor of the trade mark receives prior notice of the marketing of the repackaged product; and
- (iv) The new packaging states by whom it has been repackaged.

The re-packer has, however, to establish that the repackaging is not of such nature as to affect the original state of the product by means of, for example, only manipulating the outer packaging and leaving the inner packaging untouched as in *Eurim-Pharm*¹²⁶, or, to repackage the product under control of a public authority.

The artificial partitioning of the market was again broached in the *Paranova*¹²⁷ cases. In the first one, *Bristol-Myers Squibb v Paranova A/S*¹²⁸, the Court held that trade marks could not be exercised to partition the market but laid the burden of proof on parallel traders. In *Pharmacia & Upjohn SA v Paranova A/S*¹²⁹, the ECJ accepted that artificial market

¹²⁴ Case 107/76 *Hoffmann-La Roche AG v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH* [1977] ECR 957

¹²⁵ *ibid.*, at para. 14

¹²⁶ Case 1/81 *Pfizer Inc v Eurim-Pharm* [1981] ECR 2931. *Eurim-Pharm* packaged the blister packs in new boxes with transparent windows so that the original trademark was recognisable for the buyer.

¹²⁷ Joint cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb v Paranova A/S*, and *C H Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S*, and *Bayer AG and Bayer Danmark A/S v Paranova A/S* [1996] ECR I-3457; Case C-379/97 *Pharmacia Upjohn SA v Paranova A/S* [1999] ECR I-6927

¹²⁸ Joint cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb v Paranova A/S*, and *C H Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S*, and *Bayer AG and Bayer Danmark A/S v Paranova A/S* [1996] ECR I-3457

¹²⁹ Case C-379/97 *Pharmacia Upjohn SA v Paranova A/S* [1999] ECR I-6927

partitioning as of subjective intent is “notoriously difficult to prove”¹³⁰ and therefore the objective intent is necessary to assess. A case of market partitioning occurs if the product is only known under its trade mark name and its generic term is not used at all. However, if the use of the trade mark only serves the intention of commercial benefit as it is, for example, easier to sell the brand name “Viagra” than its generic name “Sildenafil”, the use of the trade mark is not considered to be necessary and the parallel trader is denied its use.¹³¹ As a consequence, repackaging is only allowed if it is commercially necessary in order to be able to sell the product at all.

5.1.4 Market Authorisation

In parallel trade, no second market authorisation procedure is required if the product already exists on the market of destination as the products are usually identical and will therefore conform with the same standards. The parallel imported product therefore takes advantage of the primary market authorisation on the market of destination which the originator has already gone through.

When a product is first placed on the market, there are two ways for pharmaceutical companies to obtain market authorisation, i.e. national or centralised authorisation. Market authorisation is granted when a dossier on safety, quality and efficacy of the product is being approved by the authorities.

In *national authorisation* procedures, a national regulatory authority grants authorisation in line with Council Directive 2001/83/EC¹³². It is only valid for the country of application and can not be marketed in other member states as no *automatic* mutual recognition exists. However, Council Directive 93/39/EC¹³³ provides that the first member state becomes the “Reference Member State” and sends out its authorisation documents to all other members of the Community who then have 90 days to *mutually recognise* or reject its authorisation. In case of parallel exports, the parallel trader can apply for a special licence which is granted under the general principle of EC law on the free movement of goods¹³⁴ and not under

¹³⁰ *ibid*, at para. 41

¹³¹ *ibid*, at para. 44

¹³² Council Directive 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67

¹³³ Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products [1993] OJ L214/22

¹³⁴ The strict regulatory rules since Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1965] OJ 022 have been mitigated by the case law of the ECJ, especially since the judgment in *de Peijper*.

Directive 2001/83/EC. In this case, the national authority has the duty to request information from other sources such as the market authorisation holder or the regulatory authority of the exporting country.

The parallel importer has to fulfil two requirements: The product must originate from another EU or EEA member state (specific regulation applies to the new Member States in the transition period), and it must have market authorisation in the country of exportation. Prior to 2004, common origin of the products such as production of undertakings belonging to the same group was required. This requirement was, however, removed in *Kohlpharma*¹³⁵ when the Court established that the imported and the domestic product do not have to be identical but “substantially identical” as long as there are no safety concerns. This case might potentially increase the scope of parallel trade as it might be interpreted as allowing the import of generic products – which are substantially identical – to countries where the original product is still under patent protection.¹³⁶

In alternative to national authorisation, the pharmaceutical company has the possibility of applying for a *centralised marketing authorisation* for its product in accordance with Regulation 2309/93/EC¹³⁷, amended into Regulation 726/2004/EC¹³⁸ which entered into force in November 2005 and strengthens the supervisory role of the European Medicines Evaluation Agency (EMA). This bears the advantage that the procedure is only required once and valid for all Member States which results in time and cost savings. On the other hand, it might not be the desire of the producer to obtain market authorisation during the entire Community at the same time, one reason being the prevention of parallel trade. The parallel importer benefits from centralised marketing authorisation as products are simultaneously authorised in all Member States, even if the producer does not launch them on all markets.

¹³⁵ Case C-112/02 *Kohlpharma GmbH v Bundesrepublik Deutschland* 1 April 2004

¹³⁶ Wearing, A., Kirby, I., Van Kerckhove, M., and Vodra, W. (Arnold & Porter LLP) (2004), “Parallel Trade in the EU and US pharmaceutical markets”, *Life Sciences* 2004/05, pp 117-118

¹³⁷ Council Regulation 2309/93/EC of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993] OJ L214/1

¹³⁸ Regulation 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1

Independent under which form of market authorisation the products were first launched, Directive 2004/27/EC¹³⁹ which had to be implemented by November 2005 obliges the parallel trader to give the market authorisation holder and the regulatory authorities in the country of import advance notice of his activities. If the product has not been authorised centrally, the notification can be subject to additional national procedures.

5.1.5 Conclusion

In the above mentioned cases, the Court clearly establishes the national exhaustion of IP rights such as patents and stresses the ultimate and overall aim of the Treaty, i.e. to establish a Common Market, and places the free movement of goods superior to the protection of industrial and commercial property. As soon as the patent proprietor himself or a licensee with his direct consent markets a product in a Member State, he has no possibility to object parallel imports into that State deriving from other Member States where the product is on the market.

Even though the Court touches upon the matter of rewards for the investment and innovation which the patent economically signifies, it does not actually give the patent proprietor a real chance of earning these profits as in *Merck v Stephnar*¹⁴⁰. Due to no patent protection, the product was immediately faced with harsh competition from generic producers. Though meanwhile the law was changed in Italy (since it was in fact unconstitutional), Hunter (2001) sees the same threat arising through the accession of the Central and Eastern European Countries (CEEC).¹⁴¹

In terms of trade marks, the jurisprudence of the Court is more moderate than in the case of patents. Whereas re-labelling is prohibited, simple repackaging is allowed if it is commercially necessary. Though the Court thereby opens parallel traders access to all national markets in the EEA, it nevertheless protects consumer and manufacturer interests in limiting it to basic necessities and not granting parallel traders unlimited freedom in package manipulation.

¹³⁹ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance) [2004] OJ L136/34, Art. 76 of the amended directive

¹⁴⁰ Case 187/80 *Merck & Co. Inc. v Stephnar BV and Petrus Stephanus Exler* [1981] ECR 2063

¹⁴¹ Hunter (2001), pp 31-34; Korah (2004), pp 293-298

Concerning market authorisation, pharmaceutical companies have a choice between national and centralised market authorisation procedures by which they can also take influence on the emergence of parallel trade. Special licences available for parallel traders allow them to gain market authorisation relatively easy as national institutions are obliged to obtain already available information from other sources.

5.2 Community Competition Law

5.2.1 Overview of EC Competition Law – Aims and Legal Basis

As Art. 3(1)(g) states, “a system ensuring that competition in the internal market is not distorted” shall serve the purpose of market integration. The main provisions on competition are Art. 81 and 82 which concern anti-competitive agreements and concerted practices and the abuse of dominant market positions respectively.

The purpose of competition law is twofold. Its normative aim is to ensure particular forms of competition because they are valuable for society. Its economic aim is to obtain desirable levels of competition that are unlikely to be achieved unless under legal protection. The resulting benefits for society and businesses consist of increases in wealth and innovation.¹⁴² Both aims are particularly observable in the pharmaceutical sector as innovative drugs lead to improved health and therefore a better living standard on the one hand, whereas pharmaceutical companies, on the other hand, need to make profits in order to maintain their innovation activity which is necessary and desired for modern society.

The jurisprudence of the Court defined in *Continental Can*¹⁴³ and *Metro I*¹⁴⁴ that “effective” or “workable” competition are to be obtained in the Community. In order for competition to function correctly, not only demand and supply but also price mechanisms have to function correctly. In the pharmaceutical sector, however, where national pricing regulations are predominant, the “invisible hand” of the market has little opportunity to play as this industry sector was one of the few which was not deregulated under the 1992 market harmonisation programme.¹⁴⁵

¹⁴² Gerber, D. (1998), “Law and Competition in Twentieth Century Europe”, Clarendon Press, Oxford, pp 334-391, cited after Hunter, R. (2001), p 45

¹⁴³ Case 6/72 Euroemballage Corp. and Continental Can Co. Inc. v Commission [1973] ECR 215

¹⁴⁴ Case 26/76 Metro SB Großmärkte GmbH & Co. KG v Commission (“Metro I”) [1977] ECR 1875

¹⁴⁵ Korah (2004), p 15

Patents and trade marks are not directly an issue in competition law, yet they are of indirect influence as anti-competitive behaviour is motivated by their devaluative treatment in the jurisprudence of the Court related to the free movement of goods. It should, however, not be neglected that this was necessary in order to allow the competition provisions to function correctly. In contrast to the freedom of goods, the role of the Court has been constantly decreasing in competition law while the power of the Commission and, since the entry into force of Regulation 1/2003¹⁴⁶, of National Competition Authorities have been constantly increasing.

5.2.2 Article 81 EC – Anti-Competitive Agreements and Concerted Practices

Art. 81(1) EC prohibits all agreements or concerted practices of undertakings that are anti-competitive and affect trade between Member States. For agreements to fall within the scope of Art. 81(1), three conditions have to be fulfilled: There has to be (1) an *agreement* which has (2) *intra-Community dimension* and which has (3) as its *object or effect* the distortion of competition. The Court clarified in *Consten and Grundig*¹⁴⁷ in the wording of the *Dassonville* formula that

“342. [...] what is particularly important is whether the agreement is capable of constituting a threat, either direct or indirect, actual or potential, to freedom of trade between Member States in a manner which might harm the attainment of the objectives of a single market between states [...]”

Parallel trade evidently falls under the freedom of trade. Therefore, all agreements or concerted practices that have as their objective or effect the limitation of parallel trade are void under Art. 81(1) as they hinder the basic objective of the Treaty, i.e. Common Market integration.

In early decisions and cases on parallel imports in pharmaceuticals such as *Johnson & Johnson*¹⁴⁸ and *Sandoz*¹⁴⁹, the pharmaceutical manufacturers had simply printed “export prohibited” on their price lists and invoices respectively. The ECJ upheld the Commission’s decision in *Sandoz* as it found that this practice was not an unilateral behaviour which would fall outside the scope of Art. 81(1) for two reasons: Firstly, the invoices were more than pure accounting documents as they contained further distribution terms, and, secondly, they

¹⁴⁶ Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (Text with EEA relevance) [2003] OJ 2003 L1/1

¹⁴⁷ Joined Cases 56&58/64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission* [1966] ECR 299, at para. 342

¹⁴⁸ Commission Decision 80/1283/EEC, Case IV/29.702 *Johnson & Johnson* [1980] OJ L377/16

¹⁴⁹ Commission Decision 87/409/EEC, Case IV/31.741 *Sandoz* [1987] OJ L 222, upheld by the Court in Case 277/87 *Sandoz Prodotti Farmaceutici SpA v Commission* [1990] ECR I-45

“[...] formed part of the general framework of commercial relationships which the firm undertook with its customers.”¹⁵⁰

Sandoz’ behaviour became bilateral on the ground that when the distributors received its invoices, they *tacitly* accepted its method of distribution, whether or not they actually conformed to these terms.

Whether one party abides overtly or tacitly to the practice of the other party, a *joint intention* must nevertheless exist for an agreement or concerted practice to fall under Art. 81(1). A tacit acceptance of terms cannot just be presupposed if one party acts unilaterally. In *Bayer Adalat*¹⁵¹, Bayer introduced a supply quota system for its best selling drug Adalat. Sales in the UK halved between 1989 and 1993 due to the impact of parallel trade from Spain and France. Bayer refused to supply distributors in low-price countries with the quantities they desired and thereby limited their supply. Although the distributors did not abide by these practice but constantly tried to get more supply from Bayer, the Commission found a concerted practice with regard to their long-term commercial relationship and to Bayer’s system of identifying parallel exporting wholesalers and cutting their volume of supply.

Bayer appealed to the Court of First Instance (CFI)¹⁵² and accepted that the supply quota system was introduced to stop parallel imports but denied the imposing of export bans on its wholesalers. The CFI confirmed the Commission’s findings of a unilateral concerted practice, yet it found that

“[...] measures adopted or imposed in an *apparently* unilateral manner by a manufacturer in the context of his continuing relationship with his distributors have been regarded as constituting an agreement within the meaning of Art. 85(1).”¹⁵³

Bayer’s behaviour was not merely apparent. The findings of a long-term relationship are not sufficient unless the Commission can establish the acquiescence of the dealers. However, the Commission had failed to establish a *concurrence of wills*¹⁵⁴, the importance of which was confirmed by the ECJ on appeal¹⁵⁵:

“97. [...] the CFI set out from the principle that the concept of an agreement within the meaning of Art. 81(1) of the Treaty centres around the existence of a concurrence of wills between at least two parties, the form in which is manifest being unimportant so long as it constitutes the faithful expression of the parties’ intention [...] for there to be an

¹⁵⁰ Case 277/87 Sandoz Prodotti Farmaceutici SpA v Commission [1990] ECR I-45, at para. 10, translation by Korah (2004), p 47 as the case was never fully reported in the ECR.

¹⁵¹ Commission Decision 96/478/EC, Case IV/34.279/F3 - ADALAT OJ [1996] L201/1

¹⁵² Case T-41/96 Bayer AG v Commission [2000] ECR II-3383

¹⁵³ *Ibid*, at para. 70, emphasis added

¹⁵⁴ *Ibid*, at para. 173

¹⁵⁵ Joint Cases C-2&3/01 P Bundesverband der Arzneimittel-Importeure e.V. and Commission v Bayer [2004] 4 CMLR 653

agreement within the meaning of Art. 81(1) [...] it is sufficient that the undertakings in question should have expressed their common intention to conduct themselves on the market in a specific way.”¹⁵⁶

The Court upheld the CFI’s judgment and not only increased significantly the burden of proof on the Commission, but also provided that there is no basis in case law for a general prohibition under Art. 81(1) on preventing parallel trade. The CFI specified that it is not open to the Commission to pursue its aims as market integration by straining the scope of Art. 81.¹⁵⁷

As supply quota systems are the only means to limit parallel trade which pharmaceutical companies can assume being in line with Art. 81, they are industry standard by now. Refusal to supply in exceed of local needs is either based on distributors’ past needs or past sales in monthly, quarterly or semester quotas and may either concern one or two or a few products of the manufacturer.¹⁵⁸

In *GlaxoWellcome v Commission*¹⁵⁹, GlaxoWellcome (GW) – now merged with SmithKlineBeecham into GlaxoSmithKline (GSK) – had notified the Commission of new sales conditions that it had introduced for all its products on the Spanish market.¹⁶⁰ Under this dual pricing system, wholesalers would have to pay higher prices for products destined for export than for products which were destined for the domestic market. The large majority of the wholesalers agreed to these conditions by signing the new sales conditions so that there was no question of whether an agreement under Art. 81(1) existed.

Whereas GW did not contest that this pricing system aimed at impeding parallel trade, it contested that it restricted competition due to the fact that price differences between Member States result from differences in national legislations. However, the Commission found that this practice interfered with the Community’s objective of market integration and restricted price competition for GW products. It examined an exemption under Art. 81(3) but found that the industry’s arguments were not justified. GW appealed to the CFI for juridical review where the case is still pending.

¹⁵⁶ Ibid, at para. 97

¹⁵⁷ Wearing et al (2004)

¹⁵⁸ Personal interview with Nicola Schelling of the European Commission, DG Competition, on February 21st, 2006, Brussels

¹⁵⁹ Case T-168/01 Glaxo Wellcome v Commission (pending)

¹⁶⁰ Commission Decision Case IV/36.957/F3 Glaxo Wellcome Spain [2001] OJ L302/1

5.2.3 Article 82 EC – Abuse of Dominant Position

Whereas the Court did not assess in *Bayer Adalat* whether supply quota systems may be held abusive under Art. 82, this issue was debated in *Syfait*¹⁶¹ which was not decided by the Court on substance due to a missing formality requirement¹⁶², but Advocate General (AG) Jacobs delivered his opinion on.

Art. 82 prohibits

“Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it [...] as incompatible with the common market in so far as it may affect trade between Member States.”

Hence, two conditions have to be fulfilled in order for Art. 82 to be applicable. The concerned undertaking has to be in a *dominant position* in at least a substantial part of the Common Market, and there has to be an *abuse* of its position. The Court defined a dominant position in *United Brands*¹⁶³ as

“65. [...] a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of consumers.”¹⁶⁴

To assess, however, a firm’s dominant position, the relevant market has to be determined first which consists of the relevant product market and the relevant geographical market. The former was defined by the Court in *Vitamins*¹⁶⁵ as one where

“28. [...] there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of the product is concerned.”¹⁶⁶

Product substitutability is therefore a core determinant. As there were so far no cases related to parallel imports in pharmaceuticals under Art. 82 decided by the Court, there is no guidance by case law. A direction is, however, given by the Commission in merger control cases where the relevant product market is determined based on therapeutic use substitutability. In general, products are grouped at the third level of the Anatomical Therapeutic Chemical (ATC) classification.¹⁶⁷

¹⁶¹ Case C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and others v GlaxoSmithKline* [2005] ECR I-4609

¹⁶² It was not a Greek court or tribunal that referred to the ECJ for a preliminary ruling as required by Art. 234 but the Greek competition authority. The Court therefore rejected the case so that no judgment on substance was delivered.

¹⁶³ Case 27/76 *United Brands Company and United Brands Continental BV v Commission* [1978] ECR 207

¹⁶⁴ *Ibid.*, at para. 65

¹⁶⁵ Case 85/76 *Hoffmann-La Roche & Co. AG v Commission (“Vitamins”)* [1979] ECR 461

¹⁶⁶ *Ibid.*, at para. 28

¹⁶⁷ *Wearing et al (2004)*, p 121

Substitutability of the product shall, however, consist on both supply and demand sides. This is particularly difficult to determine on the pharmaceutical market where products are patent protected. Consumers usually prefer the original products such as Valium and Viagra instead of Diazepam and Sildenafil, even after the patent protection is over. Physicians play a major role in determining the consumers' choice as they generally choose the product for their patients. Price differences between generics and original products only come into play when they are considerable and not reimbursed by the Health Insurance. Hence, original products will almost by force have dominant positions on the relevant product market.

As has been established in *Deutsche Grammophon*¹⁶⁸, the holding of an IP right does not per se constitute dominance. It might, however, coincide with particular technical advantages – which were precisely the reason for the granting of the IP right – and which may lead to a finding of dominance.¹⁶⁹

Art. 82 does not prohibit dominant positions per se but their abusive exploitation. It gives four examples of abuse, but does not define the term. The ECJ provided guidance on this matter in *Vitamins*¹⁷⁰:

“91. [...] The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is sufficient to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services based on the basis of commercial operators has the effect of hindering the maintenance of the degree of competition still existing on the market or the growth of that competition.”

The abuse of a dominant position would have been an issue in *Bayer Adalat*, had it been investigated under Art. 82, since the Court held in *Commercial Solvents*¹⁷¹ that a refusal to supply can also constitute an abuse of a dominant position. In distinction to *Commercial Solvents*, Bayer did not refuse to supply its distributors entirely but supplied limited quantities that covered the domestic market demand, whereas *Commercial Solvents* as the only producer of a certain raw material worldwide refused to supply an Italian firm entirely.

¹⁶⁸ Case 78/70 *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG* [1971] ECR 487, at para. 16

¹⁶⁹ Cases T-30/89 *Hilti AG v Commission* [1991] ECR II-1439; T-83/91 *TetraPak International SA v Commission* [1994] ECR II-755; 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission* [1983] ECR 3461

¹⁷⁰ Case 85/76 *Hoffmann-La Roche & Co. AG v Commission* (“*Vitamins*”) [1979] ECR 461, at para. 91

¹⁷¹ Joint Cases 6&7/73 *Instituto Chemioterapico Italiano SpA and Commercial Solvents Corp v Commission* [1974] ECR 223

So far, no cases in parallel imports of pharmaceuticals have been decided yet on Art. 82. As mentioned above, the first case in this issue, *Syfait*, was not decided on substance. Similar to the *Bayer Adalat* case, in *Syfait*, GSK in Greece limited its supply to exporting wholesalers considerably and started to supply hospitals and pharmacies directly. It admitted that its intention was to impede parallel trade of its products. The Greek Competition Authority applied interim measures but referred to the ECJ for a preliminary ruling. On the assumption that GSK was in a dominant position on the Greek market for at least one of its products, the epileptic drug Lamictal, and that GSK's intentions were to hinder parallel exports, the Greek Authority asked for guidance on whether a dominant pharmaceutical undertaking necessarily abuses its dominant position within the meaning of Art. 82 whenever it fails to meet in full all the orders placed with it in order to limit its customers' export activity. If not, it further asked what factors would be relevant in determining whether the conduct did in fact amount to an abuse in any particular case.

AG Jacobs argued in favour of GSK and strongly considered, in contrast to prior judgments by the Court, economic factors put forth by the pharmaceutical industry which previously were left out of scope. He concludes that

“69. [...] a dominant pharmaceutical undertaking which restricts the supply of its products does not necessarily abuse its dominant position within the meaning of Article 82 EC merely because of its intention thereby to limit parallel trade.”¹⁷²

“100. [...] a restriction of supply by a dominant pharmaceutical undertaking in order to limit parallel trade is capable of justification as a reasonable and proportionate measure in defence of that undertaking's commercial interests.”¹⁷³

As the substance of the case was not decided upon, the future directions of the Court are still unknown.

¹⁷² C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and others v GlaxoSmithKline*, Opinion of Advocate General Jacobs 28 October 2004, at para. 69

¹⁷³ *Ibid.*, at para. 100

5.2.4 Conclusion

Whereas the case law under Art. 81(1) is firmly established and delineated in detail what is possible for pharmaceutical firms to limit parallel trade and what is not, Art. 82 is still a tabula rasa in this respect and leaves space for speculation in which direction the jurisprudence of the Court will develop. The Commission certainly seems determined to prevent any limitation of parallel trade by the industry in order to pursue the aim of market integration. As long as economic arguments of the industry cannot be proved sufficiently, it will consider but not validate them. After the exploitation of Art. 81, the only further possibility it has to pursue this aim is the exploitation of Art. 82.

6 Stakeholder Analysis

This chapter provides an analysis of the stakeholders of parallel imports, based on the preceding chapters. Stakeholders are by definition “any group or individual who can affect or is affected by the achievement of the organization’s objectives”¹⁷⁴. Etymologically, the stakeholder has a stake (interest) in or is affected by something. Though the concept refers in its traditional approach to organisations and interest groups concerned by its operations (shareholders, customers, suppliers, employees, but also governmental institutions and non-governmental organisations), it has found a wider application in the last decade to certain areas of interest as for example biotechnology or biobanks.¹⁷⁵ Stakeholders with regard to parallel trade shall be identified as those directly concerned by law, economically and/or politically. The groups identified here are parallel traders, health care payers and physicians, consumers (i.e. current and future patients, tax payers), pharmacists, manufacturers and the European Commission. They are either deliberately engaging in parallel imports or affected by it through the behaviour of other stakeholders. Their respective stakes or motivations differ thereby in benefits and costs as well as legal protection, incitation or incapacity to act. The parties shall be analysed according to these parameters accordingly, taking into account both importing and exporting countries and the difference in impact of a short-term versus a long-term reflection.

6.1 Parallel Traders

The interest of parallel traders in parallel imports can be attributed first of all to the high profit margins and, secondly, to the legal facilitation of their activity. As economic theory predicts, where there are price differentials to be exploited, there will always be arbitrageurs. Moreover, additional transaction costs are low and the introduction of the Euro abolished the risk of exchange rate fluctuations at least in some countries. The alleged short-term benefits in form of cost containment for the health care sector have a demand enhancing effect and in turn motivates parallel importation. In addition to the economically low barriers of market entry and promising profits, parallel traders are favoured by both European and national legislation.

¹⁷⁴ Freeman, R. (1984), “Strategic Management: A Stakeholder Approach”, Pitman, Boston, p 46

¹⁷⁵ see, for example, Hunck-Meiswinkel, A. (2005), “Anspruchsgruppen im Innovationsprozess der grünen Biotechnologie : Analyse und Handlungsempfehlungen für Organisationen”, Nomos Verlag, Baden Baden; Scheuermann, A. (2005), “Stakeholderansatz bei Biobanken: Ländervergleich Estland – Island”, Lüneburg (Master Thesis)

The ECJ has continuously bolstered parallel import activity in its judgments both in general and in particular in pharmaceuticals for the reason of their contribution to market harmonisation. The “unnatural” factor of market convergence that does not result from free competition activity has thereby been considered as irrelevant as *Centrafarm v Sterling*¹⁷⁶ shows. Additionally, national policies in high-price countries favour parallel trade: In Germany, they basically receive a governmental sales guarantee through the legal requirement for pharmacies to sell parallel imports of at least 7% of their annual total sales. In Sweden, though no such measure is in place, incitement is high due to the incitation of other stakeholders, such as Apoteket and county councils, to distribute parallel imports¹⁷⁷ and due to the absence of policies that affect the motivation of parallel traders negatively, such as the minimum requirement in the price difference between parallel import and locally sourced products which is in place in Germany.

Parallel traders themselves mostly employ the argument of market harmonisation put forth by the Commission and confirmed by the ECJ to legitimate their activities. That this, however, does not constitute their true objective is easily graspable as complete harmonisation of the pharmaceutical market in the EU would mean the extinction of their existence as arbitrage would be rendered impossible.

On a more national level, parallel traders argue in terms of social aims such as cost reduction in the health care sector and helping patients and doctors to remain free in their choice of product and to meet budget constraints.¹⁷⁸ That their interest is less altruistic and purely economically motivated becomes apparent when looking at the destination of parallel imports. There is a clear structure recognisable that parallel traders focus on those countries with the highest price differences and where they themselves and other stakeholders are motivated by legislative measures or policies to work with parallel imports. This becomes clearly apparent in the difference in penetration by parallel imports in Sweden and Germany: After the introduction of legislative measures that require the parallel import product to be at least 15% cheaper than the locally sourced product, parallel importation rates constantly sank and are currently below 5% (2004). Parallel importers claim that this significant difference does not allow them to operate profitable anymore. But the real question is more *how* profitable.

¹⁷⁶ Case 15/74 *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.* [1974] ECR 1147

¹⁷⁷ see Chapter 6.4

Pharmacists

¹⁷⁸ Kohlfarma homepage, www.kohlpharma.com; VAD homepage, www.vad-news.org; Orifarm AB homepage, www.orifarm.se; FPL homepage, www.fpl.nu; EAEPIC homepage, www.eaepc.org; all accessed 23/04/2006.

Parallel importers clearly benefit in economic terms. As *Table 9* shows, the average mark up for 19 selected high volume products amounts to 53% in Germany and 60% in Sweden. In absolute terms, only for these products the maximum profit amounts to €97.9 (€18.5) million in Germany (Sweden) in 2002. If an average 50% mark up is assumed for the total parallel import sales in Germany of €1,000 million in 2004, then the gross profit for parallel traders to cover operating costs (including payroll, transportation, repackaging, re-labelling etc.) would be €333 million (33%).¹⁷⁹

Product(group) 2002, in thousand €	Germany		Sweden	
	Max profit for parallel importers	Average mark-up of parallel importers	Max profit for parallel importers	Average mark-up of parallel importers
HMG CoA Reductase Inhibitors (Statins)				
Atorvastatin	N/A	N/A	€1,258	53%
Pravastatin	€99	23%	€847	34%
Simvastatin	€15,067	71%	N/A	N/A
Atypical Anti-Psychotics				
Clozapine	N/A	N/A	€632	69%
Olanzapine	€31,513	47%	€2,261	76%
Risperidone	€25,718	60%	€3,090	83%
TOTAL (average) of 19 major products	€ 97,965	(53%)	€ 18,453	(60%)

Table 9: Maximum profits (in thousand €) for and average mark-ups (%) of parallel importers in Germany and Sweden for selected products, 2002
Source: Kanavos et al (2004), pp 178-179

However, none of the 12 parallel traders operating in Sweden and none of the seven major importers in Germany publish financial data on profit margins. The largest importer in Germany, Kohlpharma GmbH which has been operating in the market since 1979, nearly tripled its turnover in three years from 2000 to 2002 from €280 million to €788 million, however experiencing a drop in sales to €706 million which reflects the decreasing national parallel import rates.¹⁸⁰ The largest parallel importer in Sweden, Orifarm AB, generated sales of SEK 1,000 million in 2003.¹⁸¹

¹⁷⁹ Calculation example: if a product is purchased for €100 and sold with 50% mark up at €150, then 1/3 of the final selling price accrues to the parallel trader as gross profit.

¹⁸⁰ Kohlpharma GmbH homepage, <http://www.kohlpharma.com/unternehmen/historie.php>, accessed on 23/04/2006

¹⁸¹ Orifarm AB homepage, <http://www.orifarm.se/sw695.asp>, accessed on 23/04/2006

The only costs that can be directly measured are those of obtaining market authorisation in different Member States. The costs in Germany and Sweden are similar with €1,380 and SEK 15,000 (€1,637) respectively for an authorisation of five years which denotes annual costs of €280 and SEK 3,000 respectively.¹⁸² This does, however, not allow much conclusion on the cost structure of parallel traders, or the calculation of net profits. But it can be contended that cost for re-packaging, re-labelling and transportation are minor due to the nature of the products (small size of the packages) so that major costs accrue in administration.

Consequently, parallel distributors are incited by high profit margins made possible by national price regulations which create price differentials and by a positive, favourable legal environment for parallel imports.

6.2 Health Care Payers and Physicians

In importing countries, the benefit of the price difference between parallel imports and locally sourced products accrues to the one finally paying for them. As parallel import mainly focuses on drugs eligible for reimbursement the payer is in most cases the public health care payers who hence have a particular interest in parallel imports. In Germany, this is the SHI whereas in Sweden, county councils are responsible for drug budgets.

The constant pressure of cost containment in the health care sector makes short-term savings from parallel trade highly welcome to public payers. The higher the price difference is, the stronger is also the economic incentive for them to motivate or oblige other stakeholders to engage in parallel import. This counts not only for pharmacists who directly deliver the product to the patient and should substitute more expensive products. Decisions can already be taken beforehand by physicians who can explicitly prescribe parallel import products, both in Sweden and in Germany.

In Germany, physicians are directly under pressure to not exceed their budget and will receive malus points from May 1st, 2006 if they do not substitute. The constant shifts from centralisation of drug budgets to decentralisation and back again illustrate that the system did not work out very well, and the effects of the new regulation are obviously still unknown.¹⁸³ In comparison, decentralisation plays a major role in the health care system in Sweden and

¹⁸² Kanavos, P. and Holmes, P. (2005), "Pharmaceutical parallel trade in the UK", Civitas Institute for the Study of Civil Society, London, p 25

¹⁸³ see Chapter 4.1.2

has been working successfully. The decentralisation of drug budgets to county councils was introduced as a response to the constantly growing pharmaceutical spending. As county councils now have to pay for excessive use of drugs above the national budget ceilings out of their own budget for other purposes, they have a strong incentive to control drug expenditure.¹⁸⁴

The more health care payers and physicians are under budget pressure, the more will they substitute originals by generics and parallel imports. It has to be emphasised though that, as has been mentioned in Chapter 3.4, parallel imports and generics can be seen as substitutive measures to achieve cost containment when the patent protection period for the domestic original is over. The low level of parallel importation in Germany does not mean that cost control does not work at all, but it has to be seen in combination with the very high level of generic substitution. Vice versa, high levels of parallel importation and lower generic market shares suggest that Sweden simply lays more emphasis on parallel import substitution than on generics. However, it has also to be born in mind that parallel imports already compete with the locally sourced original when they are still under patent protection and generics are not yet on the market.

The establishment of legal measures concerning parallel imports has primarily the objective of cost containment for public bodies, i.e. to accrue to savings in pharmaceutical expenditure for health care payers. As mentioned above, the design of measures differs in Germany and Sweden. Legal measures, i.e. regulations are more pronounced in Germany, whereas Sweden sets more on incentives for payers to use parallel import substitution. When comparing mark ups of parallel importers and savings to payers, it becomes apparent that the former are the real beneficiary of those measures as their mark ups amount to ca 5 times the amount of savings to payers.

In Sweden, parallel imports are estimated to amount to a reduction in pharmaceutical expenditure of 1-1.5% (1999). It is however very difficult to show the effects of parallel trade per product group as they are vary highly from product to product. As an example of cost savings, omeprazol and lanzoprasol are calculated to amount to SEK 188 million (ca €20 million) per year (calculation period 1997-1999), and are spread on three products, Losec

¹⁸⁴ Anell, A. (2005), "Swedish healthcare under pressure", Health Economics, Vol. 14, No. 20, p 241

20mg, Losec MUPS 20mg and Lanzo 30mg, which belong to the five products amounting to 46.3% of parallel import sales. The savings are composed of the sales of less expensive parallel imports (up to 25% cheaper than the direct imports), the price cut of ca. 10% of the direct import Losec and gradually even 30% of Lanzo, and the introduction of Losec MUPS, a product which has the same active ingredient but comes in a different pharmaceutical form. It is 23% cheaper than Losec and was, in all likelihood, introduced as a reaction to parallel imports of Losec. The reduction of pharmaceutical expenses for these products amounts to ca. 19%.¹⁸⁵

The difficulty of estimating precisely the cost containment effects becomes apparent when comparing study results as calculations of total savings differ significantly. The total savings of parallel importation to the SHI in Germany amounts to less than € 100 million which corresponds to only 0.3% of the total spending on pharmaceuticals in 2003, according to the German Association of Research-Based Pharmaceutical Companies (VFA).¹⁸⁶ Persson et al (2001), which can be considered as the most accurate estimations, calculate savings of only three product to ca €20 million. Kanavos et al (2004) calculate total savings of €17.8 (€3.7) million for Germany (Sweden) in 2002 for 19 examined high volume products, i.e. 0.8% savings to the SHI in Germany and 1.3% in Sweden, but is mostly based on debatable assumptions. It does not match other data and is highly discussed in Sweden. The YHEC (2003) finally calculates savings of €194 million and €36.6 million (i.e. 78% of total savings to payers) respectively for the same year.

It has to be emphasised that the YHEC (2003) study was conducted on behalf of the European association of parallel traders, EAEP, whereas Kanavos et al (2004) were supported at least in terms of data access by Johnson & Johnson and conducted the study as a response to the YHEC study. The truth lies probably somewhere in-between.

The evident positive short-term impact of savings to the SHI has to be viewed from a long-term perspective as well. If it hinders the development of more efficient products both with respect to cost and therapeutic effect in the long run, its positive effects seem short sighted as it might imply higher cost in the long run.

¹⁸⁵ Persson et al (2001), pp 41-50

¹⁸⁶ VFA (2004)

In low-price countries, health care payers are generally not concerned by parallel trade. Yet it may lead to higher prices as well as delayed or no launches of innovative products in the long run which are more cost-effective. In this case, they incur opportunity costs since they cannot benefit from cost saving innovations.

Empirical findings shows that product launch delays of centrally authorised products due to price and reimbursement regulations and feared spill-over effects of lower prices to high-price countries amounted on average to 12.5 months in Spain and 15.8 months in Greece opposed to 8.1 months in Germany and 10.1 months in Sweden. There are also considerably less product launches in the two former countries: Out of a total of 29 products which were authorised by the centralised procedure of the EMEA, only 12 new chemical entities were launched both in Spain and Greece respectively, opposed to 21 in Germany and 23 in Sweden. This suggests furthermore that products authorised under national procedures will lead to further delay in product launches since this leaves the manufacturer the option of launch in another Member State explicitly open.¹⁸⁷ Unfortunately, there are no studies estimating the opportunity costs for product launch delays or failures for the SHI or patients.

In summary, health care payers in high-price countries benefit from parallel imports in the short term, however in minor proportion compared to parallel traders. In the long run, if there are consequences in low-price countries for these stakeholders, they are negative and consist of opportunity costs for non-available, more cost efficient medicines and a decrease in social welfare due to late or no product launches and higher prices.

6.3 Consumers: Current and Future Patients, Taxpayers

Impacts of parallel trade on consumers are not only limited to current patients, but extend also to future generations of patients as well as taxpayers. The attitude that a consumer has towards parallel imports depends thereby on his own current health situation and is influenced furthermore by his environment. If a family member or close friend has a serious illness, or a disease like cancer has a history in the family, the interest in the generation of innovative medications is significantly higher than if the person has no direct contact with such matters. His interest is then more expressed as a taxpayer in potential cost controlling effects in drug expenditure.

¹⁸⁷ Danzon, P., Wang, Y. and Wang, L. (2005), "The impact of price regulation on the launch of new drugs – evidence from twenty-five major markets in the 1990s", *Health Economics*, Vol. 14, pp 269-292

In high-price countries, current patients are concerned by parallel imports only to a limited degree, depending on the national reimbursement systems. Theoretically, they have an economic interest in parallel trade in terms of direct savings, but in practice other factors like trust play an important role in patients behaviour. Though patients have to make out-of-pocket payments both in Germany and in Sweden if they insist on the more expensive locally sourced product, many are prepared to do so. This means that even though the legislator can introduce parallel import quotas, physicians are incited to prescribe parallel imports and pharmacists are obliged or incited to distribute them, patients as end consumers still have the final say and can in their buying decision counteract the behaviour and incentives of other stakeholders. This has, however, only direct negative consequences on the sales of parallel import products, but not on cost containment for health care payers or physicians as patients bear the price difference individually. It reduces the sales of parallel traders and can have consequences for pharmacists in Germany if they cannot fulfil their quota and subsequently have to pay penalties.

In Germany, current patients usually pay fixed co-payments on reimbursement drugs so that savings resulting from the price difference accrue in general fully to the SHI.¹⁸⁸ However, after the restructuring of the reference pricing system which can include both original products and generics in one group (this is for example the case for statins which include Sortis (Lipitor)), additional co-payments amounting to the difference of the selling price and the price ceiling of the reference group have to be born by patients. Whereas generics usually require minimal co-payments as their prices lie around the reference price, significant co-payments are required for originals if they are in the same group. Patients insisting on the original can therefore benefit from parallel imports as the price difference between the latter and the locally sourced drug accrues fully to them and not the SHI. The same applies to OTC drugs and, for example, the contraceptive pill which is only available on prescription but not reimbursed. Due to savings of ca € 6 per package (normal selling price € 35 to € 50¹⁸⁹), women often ask in particular for parallel import products.¹⁹⁰ Savings on the contraceptive pill were estimated at € 10 million in 2002, dispersed on a wide range of products.¹⁹¹ Anecdotal evidence from a personal interview in a German pharmacy shows, however, that

¹⁸⁸ Kanavos et al (2004), p 100

¹⁸⁹ 6-month packages, for example Femigoa or Vallette

¹⁹⁰ Interview at Johannis Apotheke, Hamburg, 20/04/2006

¹⁹⁰ YHEC (2003)

¹⁹¹ Ibid, p 58

most patients who receive medication for high cholesterol, blood-pressure, and heart diseases do not trust parallel imports and are willing to pay higher co-payments if they can get the locally sourced drug (in case their physician explicitly prescribed a parallel import drug). This also suggests that patients' attitude towards parallel imports differs according to age groups. Whereas younger consumers perceive primarily the price advantage of parallel import drugs, older consumers perceive parallel imports as not trustworthy.¹⁹²

In Sweden, current patients can benefit in general because of the gradual progression of reimbursement rates, depending on their annual pharmaceutical consumption. The financial benefit for Swedish patients amounts to €10.1 million (2002), corresponding to 22% of total savings.¹⁹³ Patients benefit furthermore from a transparent price communication of the LFN that lists parallel imported drugs just in the same way as domestically sourced and generics.¹⁹⁴ Anecdotal evidence from a personal interview in a Swedish pharmacy and prior studies¹⁹⁵ show that like in Germany, particularly older consumers are often confused by parallel imports due to different look of packages or pills. They frequently mistrust imports and sometimes prefer to pay more to get the locally sourced original. Consumers do not ask specifically for parallel imports, but this can be explained first by the substitution policy that puts the latter on the same level as generics, and by the reimbursement system (for example, in contrast to Germany the contraceptive pill is subsidised).¹⁹⁶

Long-term effects for future patients in importing countries are identical to the above mentioned effects for the health care payers. As far as potential impacts on taxpayers are concerned, the type of national health system has to be considered. In Sweden, drug budgets and the responsibility of financing health-care services are allocated with the county councils who receive a proportion of income taxes constituting 70% of their revenues. Subsidies for prescription drugs are paid for by the national social insurance which, in turn, is financed by employer payroll fees.¹⁹⁷ Cost containment through higher sales of parallel imports could therefore be reallocated with taxpayers and would theoretically mean a decrease in taxes for them. Consequently, taxpayers would have an interest in current patients purchasing parallel

¹⁹² Interview at Johanns Apotheke, Hamburg, 20/04/2006

¹⁹³ YHEC (2003)

¹⁹⁴ LFN homepage, <http://www.lfn.se/LFNtemplates/ProductMedSearch.aspx?id=385>, accessed 27/04/2006

¹⁹⁵ Persson et al (2001), p 36

¹⁹⁶ Interview at Apoteket Svanen, Lund, 03/05/2006

¹⁹⁷ Anell (2005)

import drugs. However, considering the small impact of cost containment that has been reached, a reallocation of benefits with tax payers is in practice unlikely. In comparison, the German health system is financed by contributions to the SHI which are equally shared between employer and employee. Cost control through increased sales of parallel import drugs could therefore also mean a stabilisation or decrease of contributions rates. However, as in the case for Sweden, these are unlikely to occur.

In low-price countries, current patients are concerned by parallel exports if it exacerbates their access to medicines resulting from short-term product shortages. According to the 'public service obligation' laid down in Directive 2001/83¹⁹⁸, Art. 1(81), product shortages should not occur at all. Though there is no evidence of the magnitude of reported shortages or if they actually led to problems with access to needed medicines, there have been reports about shortages of 36 products in some parts of the Greek market which have been attributed to parallel exports.¹⁹⁹ Even if they only occur very occasionally, they are highly inconvenient for the patient. Legislative measures introduced in Greece and to a lesser degree in Spain to have an overview of parallel exports (and in Greece to secure the local supply) are however unknown of their obedience.

If parallel exports lead in the long run furthermore to delays or failures of product launches by pharmaceutical firms in order to counteract parallel trade, also future patients are concerned. The latter implies primarily a therapeutic disadvantage for patients in low-price countries compared to consumers in high-price countries but can also account to a loss of potential cost savings which might result from innovative products. In any case, it triggers a lower level of social welfare in low-price countries. In the case that more cost efficient medications are not introduced on the market and lead to opportunity costs which, in the end, are financed by taxpayers, the latter theoretically face higher charges than without parallel trade. However, these assumptions might hold in economic theory but are hard to prove in practice.

Unfortunately, there is little empirical evidence on the impacts on patients in low-price countries except for drug shortages. But if payers in importing countries would benefit at the expense of patients in exporting countries, this would not be justifiable and treatment of parallel trade by European and national institutions would have to be seriously reconsidered.

¹⁹⁸ Council Directive 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67

¹⁹⁹ Kanavos et al (2004), pp 74-75

6.4 Pharmacists

Pharmacists play a major role in parallel imports as they are the ones retailing directly to the final customer and taking the decision to substitute a locally sourced product by a parallel import sourced one (or at least offering the customer a less expensive alternative). From a purely economic point of view, dispersion of parallel imports implies opportunity costs for pharmacists as they operate at fixed margins (at least in Sweden and Germany). The dispersion of less expensive products leads therefore to a diminution of their own profit. In practice, minor discounts are offered by the wholesalers (in Germany often in form of natural rebates which have, however, been abolished from May 1st, 2006²⁰⁰). Their extent is yet unknown or can only be traced with difficulty, sometimes product specific.²⁰¹ Besides, as rebates are also offered by normal wholesalers this does not constitute an advantage over the distribution of locally sourced products. Moreover, the dispersion of drugs in different packaging or labelling and sometimes different composition of additive substances requires educational information of the patient. Last but not least, additional suppliers have to be integrated in the supply chain which increases more administrative work. In short, in economic terms parallel imports mean more work but less profits for pharmacists which consequently have no incentive to engage in them.

However, the high regulation of the pharmaceutical sector also applies to its retailers. Economic incentives are substituted by legal obligations posed on them by the state. This applies both in Germany and in Sweden, though through different legislative measures. In Germany, the by law required parallel import quota for pharmacists and impending penalties if it is not fulfilled works a disincentive to not comply with the requirement, or, put differently, as an incentive to comply with the quota, but not to disperse additional parallel imports.

A personal interview in a German pharmacy showed that pharmacists are content if they fulfil their quota since a lot of patients do not trust parallel imported products and prefer local originals, even if they have to pay higher co-payments. If the physician explicitly prescribes a parallel import, pharmacists may only substitute this by the domestic product if the patient insists on it and pays for the price difference out-of-pocket. However, parallel imports – apart

²⁰⁰ BMG (2006b)

²⁰¹ Kanavos et al (2004), pp 100 and 118

from the contraceptive pill – are often not on stock and additional time and effort are required to find a parallel distributor who has the product available.²⁰²

The low parallel import market shares in Germany confirms that legal requirements do not act as a substitute for economic incentives for stakeholders. (Private) pharmacists are still entrepreneurs whose aim is to maximise their profits, even if they work in the health sector. They will not deliberately put additional time and effort for altruistic reasons in transactions that in the end lower even their profits.

The situation in Sweden seems similar at first glance since, like in Germany, no direct economic motivation exists for Apoteket to sell parallel import products, even if it receives one-off payments at the end of the year for its work with generics and parallel imports. This fact should not be neglected but neither be considered as the primary incentive to work with parallel imports since it is only paid retroactively, i.e. Apoteket does not know the sum in advance, it cannot be attributed uniquely to parallel imports and it partly compensates for potential losses resulting from lower profits of less expensive products.

At second glance, it becomes apparent that the situation in Sweden is different for two reasons. Firstly, Apoteket is 100% state owned, and secondly, legislative measures on parallel importation are different. The public ownership suggests a stronger motivation to engage in cost containment processes such as parallel imports and to consider less its own decrease in profits resulting from that as it finally benefits the same hand, i.e. the state. Legislative measures require Apoteket to substitute originals by less expensive products such as generics or parallel imports. If the original is still under patent protection, parallel imports are the only cheaper alternative, whereas after this period, they compete with generics. That both factors influence the sales of parallel imports positively becomes apparent in their constantly increasing market share. Constantly increasing parallel import market shares over the last years which accrue to 12.2% in 2005 demonstrate that in Sweden, no legislative measure in form of a quota system is necessary as an obligation to sell parallel import products.

²⁰² Interview at Johannis Apotheke, Hamburg, 20/04/2006

In conclusion, for both Swedish and German pharmacies the direct financial benefit is zero. The only way to induce private pharmacists to cooperate in transaction where they do not benefit from economically is to oblige them by legal measures. State owned pharmacies like in Sweden work more deliberately with parallel imports, seemingly both for reasons of their public ownership and their substitution obligation.

6.5 Research-Based Industry

The stake of the research-based industry in parallel imports is first of all of economic nature since parallel imports simply mean huge losses for it. According to the industry, parts of those lost profits are basically a direct loss in R&D as they cannot be invested. Furthermore, parallel trade also has a negative impact on R&D incentives that result from its economic impact. The economic loss consists of the direct shift from market share and profits to parallel traders. To give an extreme example, as demonstrated in *Table 5* and *Table 9*, market shares of parallel import olanzapine (Zyprexa, Lilly) and risperidone (Risperdal, Janssen-Cilag) are 63% and 65% respectively in Germany with 47% and 60% mark ups of parallel traders compared to the sales price in the lowest price exporting country. In Sweden, parallel import clozapine (Leponex, Novartis; Elcrit, Pfizer) has a market share of 74% with a 69% mark up compared to the lowest price exporting country. For the latter product this means that the manufacturer only sells 26% of its products to normal prices in Sweden, and on the residual 74% receives less than 30%²⁰³ in comparison to the regular selling price.

Whereas health care payers and patients only benefit from the price difference in pharmacy purchasing price of parallel import and locally sourced products, the entire price difference between the product in the exporting country and the importing country is lost for the manufacturer, i.e. the entire mark up of the parallel trader plus savings to payers. For 19 selected products, the total loss of profitability to the industry amounts to ca €105 million in Germany and ca €21.5 million in Sweden.²⁰⁴

²⁰³ From the selling price in the low-price country, wholesaler and sometimes pharmacy margins have to be subtracted.

²⁰⁴ Kanavos (2004), pp 102 and 119

Not all manufacturers are concerned to the same degree though since parallel trade concentrates mainly on a few, highly profitable products and its impact primarily concentrates on some companies as well. In Sweden, AstraZeneca (AZ) is clearly the company suffering most of parallel trade as it produces five out of the ten parallel import products attributing the highest savings, i.e. 70% of total parallel import savings. The three most affected drugs by parallel importation are Pulmicort (AZ), Sandimmun (Novartis), and Plendil (AZ) with parallel import market shares of 93.3%, 91.8% and 80.6% respectively.²⁰⁵ In comparison, the affect of parallel trade in Germany is more dispersed on several companies. The ten most affected products are manufactured by eight different firms. The three parallel import products with highest market shares are Lamisil (72.3%, GSK), Risperdal (66.3%, Janssen-Cilag), and Zyprexa (64.2%, Lilly).²⁰⁶

The (political) objective of the Lisbon strategy, which is to render the European high technology sector into the most dynamic and competitive of the world, includes the incitation of the R&D intensive pharmaceutical sector. However, parallel trade has exactly the opposite effect on manufacturers by discouraging R&D investment. From a legal perspective, the ECJ has continuously strengthened the position of parallel traders literally at the expense of the pharmaceutical industry and never accepted its main argument against parallel trade, i.e. the detriment that is induced for R&D investment. The principle of free movement of goods has been established as *the* fundamental principle of the Treaty and been placed superior to the protection IP rights and other aims of the Community such as “the raising of the standard of living and quality of life” (Art. 2 EC) which the pharmaceutical innovations definitely contribute to largely. Therefore, irrespective of any argument the industry can put forth, as long as its objective or effect is to restrict the free movement of goods, it will not succeed. In other terms, the pharmaceutical industry is the clear loser in a situation resulting from the different regulations of Member States under the subsidiarity principle of Art. 5 and the market integration objective of Art. 2. The legal priority conflicts thereby strongly with the economic theory of social welfare maximisation. A legitimate question is therefore if market harmonisation should be pursued as a non-alternative aim even if it entails the detriment of consumers in low-price countries and also in high-price countries in the long run.

²⁰⁵ YHEC (2003), p 26

²⁰⁶ *Ibid*, p 49

As a prevention measure of parallel importation for newly launched drugs, manufacturers establish European price corridors with price bottoms and ceilings between which the price of the new drugs is allocated.²⁰⁷ Price differentials are consequently limited and do not leave an opportunity for profitable parallel trade. Due to the different price regulations of the Member States, the introduction of more uniform prices remains however difficult.²⁰⁸ If parallel importation causes manufacturers to lower prices of already marketed products is disputable. There is very little evidence that prices across countries and across individual products converged on a sustainable basis from 1998 to 2002 with the exception of some patent expired products. Moreover, price movements are also influenced by regulatory changes, currency fluctuations, patent expiry, competition by generics and different innovative treatments and other exogenous factors on specific product markets so that their exclusive attribution to parallel trade is problematic.²⁰⁹

In order to counteract parallel trade for products already on the market, the industry has introduced two main measures which are (still) allowed under the competition provisions, i.e. supply quota systems (*Bayer Adalat*²¹⁰) and dual pricing (*GlaxoWellcome v Commission*²¹¹). They seem to be effective means to contravene the export of drugs and low-prices and, at the same time, to maintain the price level on the domestic (low-price) market so that its consumers with lower income levels than in high-price countries will not face increasing prices. It hence allows the maintenance of the same level of social welfare in the low-price country as if parallel trade would not exist, whereas if parallel trade still take place (depending on the exporting price), they would still lead to short-term cost savings in the high-price countries. However, this does not solve the problem of delay or failure of product launches for those countries which are employed by firms to minimise the risk of price spillovers and to choose the option with least losses.²¹²

Hence, the industry is the clear loser in a situation where the benefits to other stakeholders are debatable. As there are no possibilities by law to thwart parallel trade, the only measures that can be taken are in terms of commercial strategy.

²⁰⁷ Persson et al (2001), p 19

²⁰⁸ Ibid, pp 34-35

²⁰⁹ Ibid, p 35; Kanavos et al (2004), p 132-134

²¹⁰ Joint Cases C-2&3/01 P Bundesverband der Arzneimittel-Importeure e.V. and Commission v Bayer [2004] 4 CMLR 653

²¹¹ Case T-168/01 Glaxo Wellcome v Commission (pending)

²¹² Danzon (2005), p 271

6.6 European Commission

The position of the Commission with regard to parallel trade is very clear cut: “We take the view that the industry is wrong first and foremost – in contending that parallel trade in medicines even harms consumers and secondly in arguing that the Commission's policy brings no benefits at all for consumers in the high-price countries.”²¹³ This is underlined by several decisions such as *Sandoz*²¹⁴, *Johnson&Johnson*²¹⁵, *Bayer Adalat*²¹⁶ and *GlaxoWellcome*²¹⁷, though not all confirmed by the Court. For the Commission, parallel trade is an instrument of market integration and it therefore backs up the operating party. Thereby it also provides parallel importers with arguments that they employ to justify their operations by their alleged altruistic nature. In contrast to the other stakeholders, the Commission is not directly linked to any economic impacts or directly obliged by law to deal with parallel trade.

Even though the Commission admits that “unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or patient”²¹⁸, its clear emphasis lies on the achievement of the objective of a Single Market inherent in the Treaty: “However, parallel trade must equally seen as an important driving force for market integration and, consequently, for achieving the Single Market.”²¹⁹ It is important to note that the Commission has, in contrast to the other stakeholders, no individual economic benefit or loss due to parallel trades. It does take side but does not gain anything from it. Its interest and benefit, i.e. market integration, is more of non-material, socio-economic nature and benefits the Community in its entirety.

A political goal of the Commission is formulated in the Lisbon strategy: “The Union to become the most competitive and dynamic knowledge-based economy in the world.”²²⁰ This includes the need for a strong, research intensive pharmaceutical sector which is still lagging behind the US. To strengthen the industry’s technological capabilities in R&D has been found

²¹³ Speech by Commissioner Mario Monti European Commissioner for Competition, “Policy Competition and Consumer: the case of Pharmaceutical Products”, Antwerpen 11 October 2001, SPEECH/01/450

²¹⁴ Commission Decision 87/409/EEC, Case IV/31.741 Sandoz [1987] OJ L 222

²¹⁵ Commission Decision 80/1283/EEC, Case IV/29.702 Johnson & Johnson [1980] OJ L377/16

²¹⁶ Commission Decision 96/478/EC, Case IV/34.279/F3 - ADALAT OJ [1996] L201/1

²¹⁷ Commission Decision Case IV/36.957/F3 Glaxo Wellcome Spain [2001] OJ L302/1

²¹⁸ Commission Communication on the Single Market in Pharmaceuticals COM (98)588 final, 25 November 1998, p 4

²¹⁹ *ibid*, pp 4-5

²²⁰ Communication from the Commission to the Council and the European Parliament, “Innovation in a knowledge-driven economy”, COM(2000) 567 final, p 4

to be a crucial priority for European competitiveness.²²¹ However, as the negative impact of parallel trade on R&D has never been concretely and satisfactorily proven by the industry, both the Court and the Commission have consistently rejected this argument. In any case, as it is a political goal, it could never be enforced in a way that is incompatible with the Treaty, that means in particular in a way that would either limit the free movement of goods or allow companies anti-competitive behaviour.

The Commission also emphasises the need for policy orientations of a Single Market in pharmaceuticals to lead to improvements in the provisions of healthcare for all citizens.²²² From the angle of economic theory, this conflicts with the strategy pursued politically and by law to favour parallel imports as they may lead to price convergence in the long run. It might in the short term entail price decreases in high-price countries, but in the long run it will also raise prices in exporting countries and further entail delayed product launches so that consumers in low-price countries will not enjoy improvements in healthcare. If, moreover, a negative impact on R&D is considered, also consumers in high-price countries cannot benefit in the long run to the same degree they would have without parallel imports. However, as these impacts are not recognised by the Commission, they are consequently not perceived as a conflict. It is however interesting that AG Jacobs defended the industry's arguments in *Syfait*²²³, although the Court did not decide the case on substance.

In short, the Commission has clearly taken position pro parallel trade and continuously corroborated it. The diverse goals that it pursues are partly conflicting due to their difference in nature, i.e. political, economic or legal composition. As a matter of course, clear priority is and has to be attributed to legal principles, but this does however not solve the complexity and controversy of the problem.

²²¹ Gambardella, A., Orsenigo, L. and Pammolli, A. (2000), "Global competitiveness in pharmaceuticals – a European perspective", report prepared for the Directorate General Enterprise of the European Commission

²²² Commission Communication on the Single Market in Pharmaceuticals COM (98)588 final, 25 November 1998, p 2

²²³ Case C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and others v GlaxoSmithKline* [2005] ECR I-4609

6.7 Conclusion

Parallel traders are the stakeholders benefiting the most from parallel trade, both in economic terms and through encouragement by law. Health care payers and patients in high-price countries, who are the actual target group of national regulations concerning parallel trade, benefit financially to a much lesser degree than parallel distributors. To who exactly the benefit accrues depends on the respective reimbursement measures. Long-term implications especially with regard to social welfare are much more disputable and are potentially negative for patients and partly for public payers in exporting, and, most probably, also in importing countries.

There is no direct economic motivation for pharmacists to engage in parallel imports (only minor ex-post compensation in Sweden) but they are instead committed by legal measures. Governments are aware of the importance of their distribution decision for parallel imports as much as of the significance of physicians' prescription behaviour. These are, in turn, incited by other measures such as budget restrictions to prescribe less expensive drugs. The final decision lies, however, always with the patient.

For the research-based industry, parallel trade simply signifies large losses due to a direct profit shift to other stakeholders and is concentrated on a couple of products and manufacturers. Since Community law does not leave much spaces for strategies to limit parallel trade, the industry increasingly sets prices on a European price corridor to the disadvantage of consumers in low-price countries.

The Commission's interest in parallel trade is of different nature as it employs it as a means to attain a Single Market in pharmaceuticals and therefore strongly takes sides with parallel traders. The fact that most benefits accrue to parallel traders and not to consumers seems not to have an impact on its positioning.

7 Conclusion

Parallel trade cannot be easily categorised since its perception as right or wrong is in the eye of the beholder and depends on whether economic, legal or political aims are pursued, whether they are viewed in a short or long-term perspective and whether the effects in importing or exporting countries are examined.

The main reason behind parallel trade are price differentials between Member States that are due to national legislation. They reflect however also differences in purchasing powers, income levels and competition effects on the market. From an economic point of view, these variables determine in combination with the price sensitivity of consumers also the most efficient strategy for manufacturers to allocate global joint R&D costs. According to economic theory, price convergence is not necessarily desirable as it would not only lower prices for importing countries but also increase them for exporting countries at the launch of new products. Furthermore, in a long-term perspective it can entail a decrease of social welfare in low-price countries and potentially also in high-price countries.

On the contrary, from a European legal perspective price differences contradict the Single Market objective and parallel imports are a means of market harmonisation that helps to converge prices, to reduce artificial market partitioning through national legal measures and to achieve the Internal Market in a sector that is still subject to the subsidiarity principle of Art. 5 and hence far from being an integrated market. A firmly established case law both with regard to the free movement of goods and the competition provisions clearly states the legal and – from a market integration perspective – desirable nature of parallel trade.

The pursuit of European political aims calls for a strong pharmaceutical industry with constantly increasing R&D investment and outputs to improve Europe's worldwide status as a knowledge-based economy, in particular in comparison to its main competitor, the US. Any actions that reduce investments or incentives in R&D such as parallel imports therefore contradict this aim. However, political aims are naturally only secondary in comparison to established legal principles.

A look on into the health care sectors in Europe illustrates that there is a strong need for cost containment measures as pharmaceutical expenditures have been constantly rising over the last decades. Two at least partly alternative ways of approaching this problem is substitution of domestic originals by generics (after the patent protection period) or parallel imports, and countries handle this substitution differently. The comparison of Germany and Sweden has shown that parallel imports are not, contrary to what is often assumed, constantly increasing in all countries. This might be predicted by economic theory as long as sufficient price differentials exists, yet the development in national regulatory environments in very recent years proved to exercise a strong influence on the actual situation. The decrease in parallel import rates in Germany and, on the contrary, its increase in Sweden reflect this.

The focus in this thesis has been laid on the analysis of stakeholders directly or indirectly concerned by parallel trade. It has shown that there are clear winners and losers as well as parties where the final balance of benefits and costs depends on the length of reflection. The highest benefits accrue undoubtedly to the parallel traders. Even though their net profit margin cannot be calculated, their mark ups suggest high margins. Further benefiting are health care payers, and current patients, yet disproportionately in comparison to parallel importers. Moreover, in contrast to the latter, payers and consumers face a trade-off between short-term and long-term reflection. Whereas benefits in the short run are evidently materialised, the long-term perspective is more blurred. The negative impact on R&D and the resulting negative impact on social welfare is not a proven fact but more an assumption based on economic theory. It is therefore hard to determine the concrete long-term impact on future patients. A fact is, however, the delay or failure in product launches in low-price countries that can be attributed to the pricing and reimbursement regulations and, as a consequence, also to parallel trade. Consumers in low-price countries are hence negatively affected by parallel trade. The influence on taxpayers in both importing and exporting countries exists more in theory but can hardly be measured in practice.

A stakeholder group that does not necessarily have any direct benefit but costs from parallel importation and yet is an important actor, are pharmacists as they are the intermediary between the parallel importer and the final costumer. Obligation but no incitation by law assures their cooperation in Germany, whereas in Sweden they work more deliberately with parallel imports and are partly compensated ex post by lump sum payments. In any case, the

additional administrative work certainly implies further cost and effort for them. In terms of retailing, physicians can also influence the distribution of parallel imports by their prescription behaviour. The stronger their budget pressure is, the more will they prescribe substitutes for domestic originals.

The clear loser in parallel imports is the research-based industry as parts of its profits are directly shifted to parallel traders and payers. Its options to counteract parallel imports are tightly regulated by law so that it has very limited measures to counteract parallel trade. The difficult question is how the R&D behaviour of manufacturers would differ if parallel importation did either not exist or were much higher. In the current status, it is difficult to assess the real impact of parallel import on R&D, yet this is a core feature of the ongoing debate.

The Commission's position as a stakeholder differs from the others as it is not directly economically involved or obliged by law to interact. However, it has an immaterial interest in parallel trade, i.e. the aim of market integration, which it pursues by strengthening the position of parallel traders.

Certainly, the subject of parallel imports in the EU has been approached extensively in former studies. A view of the relevant literature identifies legal reports which usually concentrate on the European dimension in general, economic reports which are either general or country specific, and stakeholder analyses that consider "the usual suspects", i.e. countries traditionally referred to as high-price countries as the UK, the Netherlands, Denmark, Sweden, Norway and Germany. Major recent studies such as Kanavos et al (2004) and YHEC (2003) investigate though the development of parallel imports in the end of the 1990s until the beginning of the millennium (2002) and come to the conclusion that parallel shows a constant increase in market share. Particularly since 2003 there are, however, interesting changes visible on some national markets that have not been considered before.

This thesis is distinct in its comprehensive combined approach of economic theory, European law and national regulatory environment. Whereas most studies either focus on a more legal approach (Farquharson (1998), Hunter (2001), Hays (2004)) or on a mostly economic approach (Persson et al (2001), Kanavos (2004), YHEC (2003), Ganslandt (2004)), this paper combines both fields of study. It furthermore compares two countries which are traditionally

regarded as high price countries with commonly assumed constant increase of parallel import rates due to persisting price differentials, and shows that such a stereotyping of the situation does not do justice to reality.

The comparison of Germany as a high-price country and Sweden as a country with on average more moderate price levels (though significantly high for specific products) illustrates that price differences are certainly a major, but definitely not the only determinant of parallel importation. The importance of incentives such as in the regulatory environment for involved stakeholders is often underestimated and has only been considered in detail by Kanavos et al (2004, 2005). The consideration of recently changed regulatory issues on national markets, additional data and the comparison of two countries with opposite parallel importation development allowed for an even more clear cut identification of incentives and reasoning on the behaviour of stakeholders.

The final question that remains is if short-term benefits in importing countries can justify the negative impacts of parallel trade in exporting countries. Even if arguments of the negative impacts of parallel importation are not validated as in the Commission's point of view, it is still questionable if parallel import has the desired effects of market integration in a market that is subject to national autonomy.

Prices of newly launched products are now mostly allocated on a European price corridor which implies lower prices for high-price countries but also higher prices for low-price countries. The competition effects of parallel trade are disputable and price decreases have only been shown for individual products which can, however, not necessarily be attributed exclusively to parallel import. A highly regulated market on national level that does not allow for natural competition cannot attain a sufficient level of real competition and market harmonisation through the operations of arbitrageurs. Parallel distributors are independent private agents who do not operate for public welfare. True market harmonisation can only be attained through the harmonisation of national laws. It would therefore be better to strike at the root of the problem and not to settle back and expect its side effects to cure the dilemma.

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