
UNDERSTANDING COMPETITION IN THE DISTRIBUTION OF PHARMACEUTICAL PRODUCTS IN EUROPE

**An analysis of the application of Article 82 EC to
supply-restrictions in the pharmaceutical sector**

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Much has been written and said since 31 May 2005 when the European Court of Justice said it was unable to rule in the case of Syfait and others vs. GlaxoSmithKline (GSK) Greece. This was to be a landmark case laying out the rules for applying Article 82 of the EU Treaty to the pharmaceutical sector. It was eagerly anticipated by all parties.

The Greek Competition Commission had been concerned that GSK, as the dominant player in the market for three particular medicines, was abusing its dominant position by restricting supplies of these medicines to pharmaceutical wholesalers.

The EAEPC has always believed that the behaviour of large multinational pharmaceutical manufacturers limiting the supply of medicines to pharmaceutical wholesalers is not only completely illegal under European law but morally questionable because of the risks for patient health.

We were particularly astounded when, in his opinion to the Court on 28 October 2004, Advocate General Francis Jacobs seemed to challenge years of established case law. His opinion was that a dominant pharmaceutical undertaking which restricts supplies with the intention of limiting parallel distribution does not necessarily abuse its dominant position. The opinion was not followed by the Court but has been relied upon by companies to justify anti-competitive behaviour.

I particularly welcome this report because it challenges many of the assumptions made by the Advocate General. In particular it shows that:

- Government regulation of a market does not justify private operators taking any anti-competitive measures.
- There is no evidence to suggest parallel distribution of pharmaceuticals harms R&D budgets of pharmaceutical companies or consumers – on the contrary!
- Supply restrictions that are intended to hinder parallel distribution of pharmaceuticals prevent intra-brand competition and reduce competition at the level of the pharmaceutical wholesaler and the pharmacist.
- Parallel distribution is in the interest of governments, health insurers and patients.

In short the report confirms that refusal to supply pharmaceutical products on the basis of trying to impede parallel distribution, and thus to create a foreclosure of national markets, can only be held to be abusive.

I recommend all those involved in the European pharmaceutical sector read it.



Hans Bøgh-Sørensen

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EXECUTIVE SUMMARY

This report explores how European competition rules on abuse of dominance (Article 82 EC) should be applied to the pharmaceutical sector. It concludes that European competition law should apply without restriction to the distribution in the pharmaceutical sector.

In particular the report shows that:

- Within the vertical distribution chain for pharmaceuticals the market should be defined on a one-product basis;
- Any refusal or limitation of supply that restricts parallel distribution is *per se* abusive;
- The argumentation of ECJ Advocate General Jacobs in *Syfait* concerning the justification of supply restrictions is not convincing.

The pharmaceutical market is characterised by specific features that distinguish it from other industry sectors and distribution systems. As such the economic and regulatory context in which pharmaceutical distribution takes place needs to be carefully considered and analysed.

Nevertheless, the peculiarities of the pharmaceutical market do not exclude the application of general principles of European law and in particular European competition law.

The analysis in this report focuses in particular on the parallel distribution of pharmaceuticals on the European market. Parallel distribution of pharmaceuticals is an accepted and legitimate commercial practice, and in line with the aims of the EU single market. It is a much-needed factor of competition in the pharmaceutical field, in particular regarding innovative patented medicines where it represents the sole economic competition. It generates considerable direct and indirect savings for consumers and national health systems.

Pharmaceutical wholesalers are increasingly subject to supply restrictions established by dominant pharmaceutical undertakings. These supply restrictions are intended to hinder or prevent parallel distribution of their products. They aim primarily to reduce intra-brand competition, and lead to both a limitation of competition and to a foreclosure of national markets for the distribution of pharmaceuticals.

Peculiarities of the pharmaceutical market

These refusals to supply and supply limitations by the pharmaceutical industry in order to limit parallel distribution must be assessed with particular regard to the following:

- Substitutability of pharmaceuticals

The substitutability of pharmaceuticals cannot be determined by a product analysis alone, but needs to take into account the dispensing process. Only doctors can effectively choose between therapeutically equivalent products. Pharmacists are generally limited to specific generic substitution or substitution by an identical parallel distributed product when they are presented with a prescription by the patient. If no generic is available the only possible substitution is by the original, parallel distributed product. Moreover, pharmaceutical wholesalers are neutral logistic service providers who cannot substitute pharmaceuticals at all. This structure severely restricts the individual participants of the supply chain in their

commercial activities. Compared to wholesalers or retailers in other sectors, those in the pharmaceutical sector do not have the same flexibility to supply alternative goods if they are out of stock.

- Innovation

The pharmaceutical market is characterised by a high level of innovation and large investments in R&D. However, the pharmaceutical industry benefits from considerable public financial support, and research undertaken by public researchers. In addition, it can exploit the results of R&D exclusively for the period of patent protection (up to 20 years). Therefore, arguments presented by the pharmaceutical manufacturers with respect to its R&D spending have to be placed in a critical context, in particular when used to justify anti-competitive measures. There is no quantifiable evidence that parallel distribution of pharmaceuticals negatively affects R&D spending of pharmaceutical companies.

- The regulation of pharmaceutical prices and reimbursement schemes

The regulation of pharmaceutical prices and reimbursement schemes (including patient co-payment) is not harmonised in the EU. National systems differ to some extent, this being one of many reasons for different product prices in the individual Member States. However, no matter which national regulatory system applies, there is considerable scope for the pharmaceutical manufacturers to negotiate the price of their products.

- The asymmetrical structure of supply and demand of pharmaceuticals

The demand and supply of pharmaceuticals is characterised by an asymmetrical structure. As opposed to a normal demand and supply chain, the buying and selling of a prescribed pharmaceutical product involves various actors with different decision-making functions at different stages of the process; the final consumer - the patient - plays only a marginal role in the decision making procedure. To make complete any demand-side analysis one therefore needs to consider both the decision of the doctor who decides which product to prescribe and the role of the national regulatory bodies (government/health insurance) that usually end up bearing the cost, either in full or in part.

Application of Article 82

The analysis in this report supports the basic assumption that Article 82 EC should be applied when dominant pharmaceutical undertakings engage in supply restrictions that are detrimental for competition on the market for the distribution of pharmaceuticals and damaging to the interests of consumers.

With particular reference to its application to the pharmaceutical manufacturers' policy of restricting supplies in order to limit parallel distribution, the following points should be taken into account:

- Market definition

Any analysis defining the relevant market in pharmaceuticals normally starts by evaluating the therapeutic substitutability of the product in question. Other criteria including the doctor's prescribing habits are decisive factors for this analysis. The ATC 3 classification alone is not sufficient to define a market in Article 82 EC cases.

However, the definition of the market in the relationship between pharmaceutical manufacturers and their customers must be limited to the prescribed pharmaceutical product in question. This is because of the peculiarities of the pharmaceutical market, notably the fact that it is the doctor who prescribes the

product or active ingredient and no – or very limited – substitution possibility exists for the pharmaceutical wholesaler or the pharmacist. Any approach which merely assesses theoretical therapeutic substitutability does not take these peculiarities into account and is therefore insufficient for defining the relevant market for pharmaceuticals. Any market definition needs to reflect the fact that refusal to supply a wholesaler with any pharmaceutical product will leave the wholesaler with no possibility to sell an alternative product.

There is broad consensus that, in the pharmaceutical sector, the EU member country markets are still national due to the different national regulatory systems.

- Dominance

Dominance of pharmaceutical undertakings on a one-product market is self-evident. Even if manufacturers had no or limited pricing power due to the effects of national healthcare systems on regulatory bodies' buyer power, this would not negate the existence of dominance: Firstly, pricing power is not the only parameter to establish dominance; secondly, in relation to wholesalers a pharmaceutical undertaking cannot refer to buyer power of the national regulatory bodies or any other third party.

Dominance of pharmaceutical undertakings vis-à-vis wholesalers is also established because the structure of the market makes them "obligatory trading partners". Wholesalers rely on specific products supplied by every single pharmaceutical manufacturer because of the public service obligation and the lack of substitutability.

- Abuse

Any intentional foreclosure of national markets by a dominant pharmaceutical manufacturer can only be held to be abusive *per se* under Article 82 EC since it is contrary to the EC Treaty and the concept of the single market. The two main objectives of Article 82 EC are the protection of intra-brand competition achieved through parallel distribution and the protection of the single market from division into national markets.

Furthermore, refusals to fulfil orders which are not out of the ordinary restrict the market to the detriment of the consumer and amount to discrimination with the objective of eliminating established trading partners.

Additionally, when determining the definition of an "ordinary order" the pharmaceutical manufacturers cannot simply refer to their own public service obligations in one national territory but need to fulfil orders that are part of a regular commercial practice. A wholesaler that serves markets beyond its own public service obligation – no matter if they are inside or outside its national territory – engages in just such a regular commercial practice. Such activities cannot be deemed "out of the ordinary".

This report also reminds us that for any argument the pharmaceutical industry presents to justify its abusive behaviour it has the burden of proof. Arguments presented so far by the pharmaceutical industry fail to withstand a careful analysis. Indeed, so does the opinion of ECJ Advocate General Jacobs in *Syfait*.

I INTRODUCTION

1. EAEPCC – The European Association of Euro-Pharmaceutical Companies

The European Association of Euro-Pharmaceutical Companies (EAEPCC) is the professional and representative voice of pharmaceutical parallel distribution in Europe. It was founded in June 1998, as a body to represent the interests of distributors engaged in the cross-border distribution of medicines within the European Union and European Economic Area. Today it encompasses around 70 companies represented individually or by national associations from 17 countries in the European Economic Area (EEA).¹

The primary aims of the EAEPCC are to safeguard the free movement of medicines, as laid down in Article 28 EC, and to counteract any attempts to restrict the freedom of choice for the consumer through trading patterns in breach of Articles 81 and 82 EC. Its objective is to develop and maintain a convincing, consistent and transparent policy, ensuring that the socio-economic benefits of professional parallel distribution are perceived, understood and acted upon by national governments, health insurance organisations, European institutions, and the wider public. The EAEPCC seeks to ensure that the social policies of the EU and its Member States accept and actively use the benefits of professional parallel distribution. For that reason it promotes and co-operates in the development of parallel distribution as a means of completing the EU internal market, providing innovative medicines to all Europeans at affordable prices.

The Association believes that free trade will lead to improvements in health standards through the provision of innovative medicines at lower cost, benefiting statutory healthcare systems, other third-party payers, and the public as both patients and taxpayers, as well as assisting the EU to achieve its objective of a single integrated market.

2. Parallel distribution of pharmaceuticals – the background

Parallel distribution is the cross-border sales of goods. It is known as ‘parallel’ to the extent that it takes place outside and – in most cases - in parallel with the distribution network that the manufacturers or original suppliers have established for their products in a Member State, while it concerns products which are identical to the ones marketed by the distribution networks.² Parallel distribution of all sorts of products, including pharmaceuticals, occurs when products are purchased in a country where they are cheaper and transported for resale to other countries where they are more expensive.³ On the import market parallel distributed products compete with the same product sold by the manufacturer or its licensee. Parallel distribution exists and will exist wherever there are sufficient price differentials.

The incentive for parallel distribution appears when the price differential exceeds the costs of trading the good across borders. The main reasons for price differentials and hence opportunities for arbitrage in general are the following:⁴

- Variations of national intellectual property rights protection, so that a product may remain under patent for longer in one jurisdiction than in a neighbouring

¹ A list of members is available at www.eaepc.org.

² Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, COM (2003) 839, p. 6.

³ *Helena Tobin, Neil Turner, Parallel Trade 2003 – a concise guide*, 2003, p. 6.

⁴ See: *Jacob Arfwedson, Re-importation (Parallel Trade) in Pharmaceuticals*, IPI Centre for technology freedom, 2004, p. 5.

jurisdiction. In the latter jurisdiction, the product may then be subject to competition from generic suppliers, driving down the price of the branded product.

- Variations in purchasing power, per capita income and preferences affect demand and market size. Also rebates negotiated by government or donations of medicines can lead to substantial price differences.
- Variations in the nature of price regulation.
- Differing inflation rates, which create exchange rate differentials, which, combined with national price measures, may translate into retail price variations.
- Tax rates, notably sales taxes, may motivate differential international pricing to ensure efficient sales.
- The patent holder may develop various marketing and sales strategies with corresponding price differences for selected markets.

Parallel distribution of pharmaceuticals in the EU is based on most of those incentives. Still, it is in particular the principle of free movement of goods enshrined in Article 28 EC that paved the way for parallel distribution of pharmaceuticals within Europe.⁵ The free movement of goods permits pharmaceuticals to be traded freely throughout the EU, and indeed the EEA area, without the threat of tariff or non-tariff barriers. These rules, in combination with the principle of exhaustion of intellectual property rights, a rule chosen by the EU for further integration of the single market, provide a legal framework across the EEA conducive to parallel distribution.

Parallel distribution of pharmaceuticals has always been an accepted and protected commercial practice within the Community. The European Commission recently noted that:

*"Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations provided by article 30 of the EC Treaty."*⁶

This approach has been consistently backed by the European Court of Justice (ECJ), whose rulings have repeatedly confirmed that medicinal products are not exempted from the rules of the internal market.⁷ Therefore, over the last 30 years, the Court has condemned various state measures which restrict, without appropriate justification, parallel imports of medicines.⁸

The case law dealt in particular with the requirements and procedures for authorising parallel imports.⁹ It clarified further that the owner of a national patent right may not rely on its right provided by national legislation to oppose the importation of a product which has been lawfully placed on the market in another Member State by, or with the consent of, the

⁵ *Helena Tobin, Neil Turner, Parallel Trade 2003 – a concise guide, 2003, p. 6.*

⁶ Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, COM (2003) 839, p. 6.

⁷ Case 15/74, *Centrafarm v. Sterling*, (1974) ECR 1147; Case 16/74, *Centrafarm v. Winthrop*, (1974) ECR 1183; Joined Cases C-267/95 and C-268/95, *Merck v. Primecrown*, (1996) ECR I-6285, para. 47; Case C-436/93, *Bristol-Myers Squibb v. Paranova*, (1996) ECR I-3457.

⁸ The Court thereby not only focused on measures against parallel distribution on the wholesaler level but also on the pharmacists level, like in Case C-322/01, *Doc Morris*, (2003) I-14887.

⁹ Case 104/75, *De Peijper*, (1976) ECR 613; Case 247/81, *Commission v. Germany*, (1984) ECR 1111; Case C-201/94, *Smith & Nephew*, (1996) ECR I-5819; Case C-94/98, *Rhône-Poulenc*, (1999) ECR I-8789; Case C-172/00, *Ferring*, (2002) ECR I-6891; Case C-112/02, *Kohlpharma*, (2004) ECR I-3369.

proprietor of that right.¹⁰ Furthermore, the ECJ has condemned the use of trademark rights to prevent parallel importation.¹¹

The ECJ has further noted that national price control systems, although not in themselves contrary to the principle of free movement of goods, may nevertheless be challenged when prices are fixed at such levels that the sale of imported products becomes either impossible or more difficult than the sale of domestic products.¹² It concluded as well that:

*"distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules on free movement of goods"*¹³

Parallel distribution is, however, not only the exploitation of a pure arbitrage opportunity but a valuable tool of cost control in the health care sector throughout Europe. Parallel distributors have invested over the time substantially in setting up efficient distribution networks to supply consumers in various Member States with high quality medicinal products at lower prices. In doing so they take entrepreneurial risks, in particular the risk of price reductions or that the product does not sell. This can be due to either consumer resistance or the domestic suppliers modifying their selling price. Since it can take many months to gain a license to distribute a product, distributors face an additional risk that price reductions occur before the product can be legally supplied.¹⁴

Parallel distribution in general, and parallel distribution of pharmaceuticals in particular, is therefore a commercial business that uses market mechanisms to buy and sell products in different countries. It is a practice which is very much in line with the aims of the EU's single market and which introduces a valuable element of competition within the EU.

3. Initiatives of the pharmaceutical industry to limit parallel distribution

Contrary to the jurisprudence of the ECJ that defends parallel distribution as a lawful form of trade in the internal market, the pharmaceutical industry endeavours to implement strategies and mechanisms that directly impede parallel distribution of its products. These mechanisms aim in particular to directly or indirectly control distribution in the export countries to prevent resale in other Member States. Typical measures include:

- Sales conditions with different prices for national sales and exports¹⁵ (dual pricing);
- Quota systems which e.g. refer to sales in previous years¹⁶ (quota systems);
- Limitation or refusal to supply wholesalers¹⁷ (refusal to supply).

¹⁰ Case 187/80, *Merck v. Stephar*, (1981) ECR 2603; Case C-191/90, *Generics and Harris Pharmaceutical*, (1992) ECR I-5335, Joined Cases C-267/95 and C-268/95, *Merck v. Primecrown*, (1996) ECR I-6285.

¹¹ Joined Cases C-427, 429 & 436/93, *Bristol-Myers Squibb*, (1996) ECR I-3457, Case C-232/94, *Rhône-Poulenc*, (1996) ECR I-3671; Case C-379/97, *Pharmacia & Upjohn*, (1999) ECR I-6927; Case C-143/00, *Boehringer etc.*, (2002) ECR I-3759; Case C-443/99, *Merck, Sharp and Dohme vs Paranova*, (2002) ECR I-3703.

¹² Case 181/82, *Roussel Laboratoria*, (1983) ECR 3849.

¹³ Joined Cases C-267/95 and C-268/95, *Merck v. Primecrown*, (1996) ECR I-6285, para. 47.

¹⁴ See also *Peter West/James Mahon*, Benefits to Payers and Patients from Parallel Trade, 2003, p. 1.

¹⁵ See Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001) p. 1, para. 1.

¹⁶ Décision du conseil de la concurrence no. 04-D-05, 24 February 2004 (Phoenix Pharma).

¹⁷ See Commission Decision of 10 January 1995, Case IV/34.279/F3 – Bayer/Adalat, OJ L 201 (9.8.1996) p. 1, para. 153. Decision 193/III/2001 of 3 August 2001, Glaxo Wellcome, GRURInt 2002, 534. A

These kinds of measures normally reflect individual decisions of undertakings and are not based on or supported by any state measures. The most recent exemption is Spain where a initiative proposed by the Spanish legislator facilitates the pharmaceutical undertakings in preventing exportation of their products.¹⁸ Whereas such state measures are subject to Article 28 and 30 EC the legality of individual decisions of undertakings needs to be assessed under European competition law or the national equivalent of Article 81 and 82 EC.

In this respect the *Bayer/Adalat*¹⁹ ruling from 2004 is certainly a key decision. The ECJ decided that a decision to limit supply imposed unilaterally in a continuous business relation does not amount to an agreement in breach of Article 81 EC. The case concerned a quota system implemented by Bayer whereby it limited the supply of its product Adalat to certain wholesalers in France and Spain. However, the Court did not rule on the assessment of such behaviour under Article 82 EC since it was not part of the appealed Commission decision. Therefore, the decision did not elaborate on the issue of a possible dominant position of Bayer or on the abusive character of the supply limitation.²⁰ Furthermore the Court only considered the specific circumstances of the case, namely the complaint alleging the existence of an agreement. It thus remains an open question to which extent the decision will have an impact on future cases.

Nevertheless, the *Bayer/Adalat* decision led to an intensive discussion and numerous comments on how the pharmaceutical industry could use allegedly "legal" possibilities to restrict parallel distribution.²¹ In particular the fact that a unilateral measure could still be anticompetitive under Article 82 EC raised the question how far the industry could go in practice.

First guidance was expected from a preliminary rulings procedure initiated by the Greek Competition Commission in a case called *Syfait*.²² The case concerned a total supply stop of six months and further supply limitations with regard to three pharmaceutical products of GlaxoSmithKline Greece (GSK). GSK's intention behind these supply restrictions was to prevent any further parallel distribution of those three products. The ECJ, however, declared the case inadmissible in May 2005 after Advocate General Jacobs gave a highly controversial opinion about the case in October 2004.²³

Jacobs considered that, due to the peculiarities of the pharmaceutical market, a refusal by a dominant undertaking to supply with the intention of preventing parallel distribution could be considered as non-abusive and justified. This opinion, however, has no legally binding effect and is merely the interpretation of an independent attorney integrated in the

preliminary rulings procedure referring to this case has been rejected as inadmissible by the ECJ (C-53/03, *Syfait*, judgment of 31 May 2005).

¹⁸ Draft Royal Decree of 16 May 2005 amending Royal Decree 725/2003; see also: Spain: review of Pfizer's direct distribution and dual pricing plans, PHARMA Pricing & Reimbursement (PPR) 2005, p. 192.

¹⁹ Joined Cases C-2/01P and C-3/01, *Bundesverband der Arzneimittelimporteure v Bayer AG*, (2004) ECR I-23.

²⁰ *Wolfgang A. Rehmann*, Kein Freibrief für Kontingentierungsmaßnahmen der Pharmazeutischen Industrie, PharmR 2004, p. 76; Joined Cases C-2/01P and C-3/01, *Bundesverband der Arzneimittelimporteure v Bayer AG*, (2004) ECR I-23, para. 42.

²¹ *Marleen van Kerckhove*, Parallel trade in pharmaceutical products following the ECJ's Bayer judgement: Can a case be made under Article 82 EC?, *The European Antitrust Review*, 2005; *Stephanie Pautke*, *Keith Jones*, Competition Law limitations for the distribution of pharmaceuticals – rough guide to the brave world, ECLR 2005, 24; *Patrick Rey*, *James Venit*, Parallel Trade and pharmaceuticals: a policy in search of itself, ELR 2004, 153; *Ulrich M Gassner*, How recent changes in EU competition and pharmaceutical law will affect parallel trade, RAJ Pharma 2004, p. 655.

²² Case C-53/03, *Syfait*, judgment of 31 May 2005.

²³ Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, *Christian Koenig*, *Christina Engelmänn*, Parallel Trade Restrictions in the Pharmaceutical Sector on the Test Stand of Art. 82 EC: Commentary on the Opinion of Advocate general Jacobs in the Case *Syfait/GlaxoSmithKline*, ECLR 2005, p. 338.

structure of the Court. The final outcome of the case was thus a disappointment for all those who were hoping to receive further guidance on this issue. Still, the pharmaceutical industry has tried to suggest that the Advocates General's opinion is the authoritative word for the time being.²⁴ The study will therefore also reflect on the arguments discussed by Jacobs and will show that they are based on wrong and misleading assumptions.

Despite the persisting legal uncertainty, the judgment in *Bayer/Adalat* and the opinion of the Advocate General in *Syfait* the pharmaceutical industry continues to implement a rigid and aggressive supply policy, introducing quota systems and supply limitations across Europe.²⁵ Some examples²⁶ shall be mentioned:

- Since 2003, AstraZeneca has applied quota systems for a number of products in Spain, Portugal, Belgium and Italy. In France and the Netherlands it refuses to supply certain products.
- Since the end of 2002, GlaxoSmithKline has subsequently introduced quota systems in Spain, France and Italy for a number of products.
- In 2002, Lilly implemented a quota system in Belgium, Portugal, France, Italy and Spain for particular products.
- In 2002, Pfizer introduced a quota system for some of its products in Portugal, France and Belgium.
- Sanofi-Synthelabo (now Aventis) implemented a quota system for a number of products in Portugal, Spain, Greece, Belgium and France in 2002.

While these facts are well known in the market there is still reluctance on the side of the various competition authorities to proceed against such behaviour which is clearly anti-competitive.

4. Aim of the study

This study investigates the initiatives of the pharmaceutical industry to hinder parallel distribution by unilateral measures to limit supplies to wholesalers²⁷ under Article 82 EC.

Article 82 EC provides that:

"Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States."

Whilst there have been no further decisions yet at a European level to address this particular problem, the debate nevertheless rages on with great intensity. Despite the pending case on dual pricing by Glaxo Spain,²⁸ there are further complaints on quota systems and on refusals to supply pending with the Commission. It is therefore only a

²⁴ See e.g. *Erwin Krapf, Barbara Lange, Staatliche Intervention, duale Preissysteme und europäisches Kartellrecht*, PharmR, 2005, p. 321.

²⁵ See e.g. a note of the BPI (Bundesverband der pharmazeutischen Industrie e.V.) the German Association of the Pharmaceutical Industry from 31 May 2005 that advises pharmaceutical undertakings who would envisage to take action against parallel distribution of their products to opt for the system used by Glaxo in Greece.

²⁶ The examples are based on information received from EAEPC members. A complaint against these measures is pending with the European Commission.

²⁷ This study is not dealing with dual pricing or other initiatives limiting parallel distribution.

²⁸ See Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001) p. 1 now pending at the CFI, Case T-168/01, OJ C 275 (29.9.2001) p. 17.

question of time until the ECJ or the Commission will have to decide on this issue. Following the Bayer/Adalat judgement the Commission announced that it would continue to monitor the behaviour of the industry²⁹ and would give more importance to the application of Article 82 EC. However, with the decentralisation of competition law, national authorities and national courts are also asked to effectively implement European competition law in the Member States. If they have not done so already, they will have to decide cases on the abuse of a dominant position in the pharmaceutical sector.

In the light of the ongoing debate, this study aims to contribute to a better understanding of the factual background concerning the parallel distribution of pharmaceuticals as part of the overall distribution of pharmaceuticals and to provide a thorough analysis of the legal problems involved when pharmaceutical undertakings refuse to supply or introduce quota systems.

For that reason the study will set out in detail the general conditions and characteristics of pharmaceutical distribution in the economic and regulatory context and will establish criteria that define the market for pharmaceutical distribution. Furthermore it will discuss the market power of pharmaceutical undertakings and explain why behaviours as set out above are abusive and contrary to Article 82 EC.

²⁹ *Daniel Dombey and Nikki Tait*, Court rules Brussels wrong to sanction Bayer Antitrust Law, Financial Times, 7. January 2004.

II THE PHARMACEUTICAL MARKET

1. Scope of evaluation

As the chapter on market definition will show there are numerous factors that have to be taken into account when assessing a market in the pharmaceutical sector. Therefore, the evaluation shall be limited to factual circumstances in which most of parallel distribution of pharmaceuticals is carried out.

Based on the economic context in which parallel distribution can take place (see chapter I, section 2.) this study investigates restrictive measures of the pharmaceutical industry by focussing on a particular group of products which meet certain characteristics.

1.1 *Patent protected medicines*

The scope of the following evaluation will be limited to products that are still under patent protection. This is due to the fact that in the absence of generics on the market the intra-brand competition by parallel distributed products is the most valuable. It is the only source of competition for patented pharmaceuticals and therefore of the most benefit for the consumer. However, even parallel distribution of generics is possible to a limited extent. Nonetheless, this factor shall be likewise disregarded in the following analysis. Also, the question whether generics are substitutes for patented drugs will not be further discussed.³⁰

1.2 *Prescribed and reimbursed medicines*

Most of the parallel distributed products are further subject to prescription and reimbursement. The Commission considered the interaction between prescribed and over-the-counter (OTC) pharmaceuticals as well as reimbursed and not reimbursed medicines as follows:

"These segments overlap to a certain extent. Most of "prescription only" medicines are reimbursed and most of "sold freely" medicines are not reimbursed. Moreover, the presence of a medicine in one of these segments is not permanent to the extent it is linked to decisions of national authorities, often at the request of companies, which can lead to switches between these segments."³¹

As the Commission has clarified there are different markets for prescribed and OTC products that might be further subdivided into markets for reimbursed and non-reimbursed pharmaceuticals.³² However, for the following analysis, it will not be necessary to go into detail on this question as most parallel distributed pharmaceuticals are products subject to prescription and reimbursement.

³⁰ For further information on this issue see e.g.: *Howard Morse*, Product market definition in the pharmaceutical industry, 71 *Antitrust L.J.* 2003, p. 633 with further references to case law.

³¹ Commission Decision of 6 September 1994, Case IV/M.464 – BMSC/UPSA; Commission Decision of 28 February 1995, Case IV/M.555 – Glaxo/Wellcome; Commission Decision of 16 July 1996, Case IV/M.737 – Ciba-Geigy/Sandoz; Commission Decision of 4 February 1998, Case IV/M.950 – Hoffmann La Roche/Boehringer Mannheim.

³² See e.g. Commission Decision of 8 May 2000, Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham; Commission Decision of 22 May 2000, Case COMP/M.1878 – Pfizer/Warner-Lambert; Commission Decision of 27 February 2003, Case COMP/M.2922 – Pfizer/Pharmacia.

1.3 *Final scope of evaluation*

Research shows that parallel distribution mostly takes place where the above mentioned criteria cumulate, thus in the supply with patent protected, reimbursed and prescribed pharmaceuticals. The regulatory conditions for these products together with the above mentioned general incentives for parallel distribution favour the intra-community trade with pharmaceuticals.

The same regulatory conditions have to be taken into account when assessing anticompetitive behaviour on the pharmaceutical market since they not only affect the market behaviour of the parallel distributors but also of the pharmaceutical industry.

Pharmaceuticals that are patent protected and subject to reimbursement regulation and prescription are to a certain extent subject to specific market conditions. While these do not preclude the application of the competition rules they will need to be considered in their application. Therefore, the following study will focus in particular on these conditions and how they influence an assessment of Article 82 EC.

For the reasons mentioned above this study will focus on prescribed and reimbursed pharmaceuticals that are still under patent protection.

2. Rules and Regulations characterizing the pharmaceutical markets

The pharmaceutical market has a number of distinct characteristics that should be considered in any evaluation of anti-competitive behaviour. Only a core understanding of the complexity of issues in the pharmaceutical market can lead to a comprehensive analysis. Therefore, this chapter will give some information on how prices and reimbursement are regulated by the Member States and how Member States regulate the dispensing of pharmaceuticals as a way of cost containment measure. First of all, however, it shall be briefly explained why regulation of prices and reimbursement takes place.

2.1 *Price discrimination and market failure*

In Europe all Member States bear the responsibility for public health and must secure health policy objectives. These objectives include health protection; guaranteeing patients universal access to safe and effective medicines and improving the quality of care and a system of social security to finance it. Governments have a public interest to ensure that pharmaceutical expenditure does not become excessive since this could undermine these and other government objectives.³³

Governments have to balance market imperfections both on the supply side (related to patent protection, the process and length of regulatory approval) and the demand side (as it will be shown below, there is a four-tiered structure of demand where the doctor prescribes, the pharmacist dispenses, the patient consumes and the health insurance pays).³⁴ In particular the price inelasticity of demand combined with the guaranteed access to effective medicines is one of the stumbling blocks of the market. These imperfections in the supply and demand of pharmaceuticals lead to market failure.³⁵

³³ *Elias Mossialos, Monique Mrazek, Tom Walley, Regulating pharmaceuticals in Europe: an overview in Elias Mossialos, Monique Mrazek, Tom Walley (Ed.), Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 1.*

³⁴ *Elias Mossialos, Monique Mrazek, Tom Walley, Regulating pharmaceuticals in Europe: an overview in Elias Mossialos, Monique Mrazek, Tom Walley (Ed.), Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 2.*

³⁵ See e.g. *Jürgen Wasem, Stefan Greß, Dea Niebuhr, Regulierung des Marktes für verschreibungspflichtige Arzneimittel im internationalen Vergleich, 2005, p. 48.*

Member States attempt to correct those market imperfections and to control other factors that lead to rising drug expenditures through cost-containment measures on the supply side of the market, mainly in the form of price controls and reimbursement regulations. In addition, governments also use demand-side measures such as financial incentives, quantity controls and educational initiatives for doctors.³⁶

The ECJ has acknowledged that, in the absence of harmonisation, Member States are entitled to set the prices of pharmaceutical products in order to guarantee to all citizens equal access to medicinal products and to safeguard the financial stability of their social security services provided that such an intervention does not discriminate *de jure* or *de facto* between national or imported products and the price indicated is remunerative.³⁷

The industry on the other side promotes a pricing system that has as its basis price discrimination. It argues that the interests of all parties – payers, patients, the public overall, as well as manufacturers – would be best served by spreading a product's total development and production costs differentially.³⁸ This is supported by the economic theory of Ramsey pricing which states that efficient pricing requires sharing sunk costs. The principle implies that, contrary to common presumption, charging all payers the same price is not optimal. Rather, users whose demand is relatively price inelastic should pay higher prices than payers whose demand is relatively price elastic. Total revenues are higher with differential pricing, both because those payers with higher valuation pay more and because those with low valuation stay in the market.³⁹

The effect of price discrimination can be best seen in the US where prices are freely set by the industry.⁴⁰ Only when the industry is negotiating with favoured buyers – such as special health maintenance organisations or the federal government, which is paying for medicines for government officials (e.g. soldiers) – prices are set at a lower level. Often these big consumer groups can negotiate rebates and discounts that are not available for individuals.⁴¹ Patients that do not belong to these favoured consumer groups and do not have an insurance coverage for medicines therefore have to pay the highest prices. The elderly represent a particularly large share of this group. In fact, price differences between favoured buyer prices and average retail prices could amount up to 1566% (sic).⁴²

2.2 Price regulation, reimbursement & patient co-payment

(a) Introduction

Price regulation for pharmaceuticals in Europe is characterised by different national approaches and systems since public health remains an area of national competence.

³⁶ *Elias Mossialos, Monique Mrazek* Regulating pharmaceutical prices in the European Union in *Elias Mossialos, Monique Mrazek, Tom Walley (Ed.)*, Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 114.

³⁷ Case 181/82, *Roussel Laboratoria*, (1983) ECR 3849 and Case 249/88, *Commission v. Belgium*, (1991) ECR I-1275.

³⁸ EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004, p. 15.

³⁹ See e.g. *Patricia Danzon*, Price discrimination for pharmaceuticals: welfare effects in the US and the EU, *International Journal of Economics of Business* 1997, p. 301.

⁴⁰ For the US system see e.g. *John Hansen*, United States – prescription drug prices and reimbursement policy, chapter in the LSE survey from 2001 on the Commission webpage <http://www.pharmacos.eudra.org>.

⁴¹ *Jürgen Wasem, Stefan Greß, Dea Niebuhr*, Regulierung des Marktes für verschreibungspflichtige Arzneimittel im internationalen Vergleich, 2005, p. 58 et seq.

⁴² Prescription drug pricing in the United States: drug companies profit at the expense of older Americans, report prepared for the House of Representatives, 9.11.1999; *Jary Flanagan*, A cure for rising health care costs: prescription drug buying pools, 2001; *Marcia Angell*, The truth about the drug companies: how they deceive us and what to do about it, 2004.

Reimbursement regulation and the level of patient co-payment likewise vary between the individual Member States. As the Commission noted:

*"Member States have exclusive responsibility in the field of health care; they view the provision of health and its financing as keys to social security; and they have to meet public expenditures objectives (...)"*⁴³

The only EU legislation concerned with pharmaceutical prices, the Price Transparency Directive,⁴⁴ was designed merely to obtain an overview of national pricing and reimbursement arrangements and to ensure that these were operated in a fair, timely and transparent manner. It was not an attempt to harmonise prices or national systems, but rather to establish framework requirements that allow companies and the European Commission to verify that national measures do not represent quantitative restrictions on intra-community trade.⁴⁵

The differing approaches reflect distinct national policy priorities: the need to contain pharmaceutical expenditures; the extent and characteristics of regulating the demand for pharmaceuticals; and the relative weighing of health policy and industrial policy objectives (for example, promotion of pharmaceutical research and development, employment, a positive balance of trade).⁴⁶

National price regulation is usually closely connected to the national reimbursement policy. Therefore, both topics need to be considered always in relation to each other. In most countries, national law foresees that a pharmaceutical may only be sold at a single price and restricts market access for pharmaceuticals without reimbursement. If medicines are fully reimbursed, controlling the price is the only way of limiting the amount paid by the national health insurance, unless Member States opt for controlling profits like in the UK.

The industry, on the other hand, has an obvious commercial interest to have their products listed in the national reimbursement scheme since it is a competitive advantage towards non-reimbursed products that are therapeutically identical. As it will be shown below (see section 3), the price of a pharmaceutical does not play the same role for the choice of a product as for other products. As long as the product is reimbursed, the patient does not reflect about the price of the product, nor, generally, is the price crucial for the doctor's decision.

Annex I provides a short overview on national price regulation systems and **Annex II** shows how some of the Member States regulate their reimbursement schemes in the most relevant import and export states for parallel distribution. Without aiming to give a complete picture of price and reimbursement regulation in Europe, this overview is intended to set out some general principles that show the intention and effects of price and reimbursement regulation.⁴⁷

⁴³ Commission Communication on the Single Market in Pharmaceuticals, COM (98) 588, p. 2.

⁴⁴ Council Directive 89/105 of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems; OJ L 40 (11.2.1989) p. 8.

⁴⁵ Leigh Hancher, The European Community dimension: coordinating divergence in *Elias Mossialos, Monique Mrazek, Tom Walley (Ed.)*, Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 60.

⁴⁶ *Elias Mossialos, Monique Mrazek* Regulating pharmaceutical prices in the European Union in *Elias Mossialos, Monique Mrazek, Tom Walley (Ed.)*, Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 115.

⁴⁷ The Commission has published the findings of an LSE survey from 2001 on its webpage <http://www.pharmacos.eudra.org>.

What becomes obvious is that no two national systems are the same and no country relies on a single approach.⁴⁸ Furthermore, national systems are constantly in a state of change. While governments may seek ideas for solutions from the experience of other countries, new cost containment measures are layered on top of previously unsuccessful ones, further widening the divergence. However, one can extract the following general principles.

(b) *Price regulation*

Price regulation policies that are applied in the Member States either as a single approach or as a combination include:

- price negotiations between the authority and the applying company;
- price proposals by the company upon the approval of the authority;
- free pricing but restrictions on reimbursement levels;
- profit control;
- unilateral price fixing by the approving public health authority.

Further, health authorities in almost all countries tend to use national and international comparative indicators to establish prices. They either refer to prices of products that are considered to be essentially similar (reference pricing) or to the price of the same product in another Member State (cross-country comparison).

- reference pricing

In a system that uses reference pricing, products that produce similar clinical outcomes are grouped, and a reimbursement maximum per group is set. The patient will be required to pay any excess if a product more expensive than the group's reference price ceiling is prescribed. Some countries limit reference pricing to patent-expired molecules when generic competition is established. The Netherlands and most recently Germany also include patented products along with off-patent products when these are deemed to be interchangeable.

- cross-country comparisons

Most countries that intervene in pricing look to other (peer) countries to see what prices exist there. For instance in Portugal the initial manufacturers' maximum selling price is based on the lowest price of an identical or similar pharmaceutical product containing the same active ingredient in three reference countries (France, Italy, Spain). This approach is not limited to Europe. For example, Canada references against six, and Japan against four, European countries. This explains why companies are keen to avoid a low price in any national market, no matter how small, as this can have global knock-on repercussions.

The authorities will further consider different other criteria like cost-benefit effectiveness proven by sufficient data, therapeutic value, the complete costs, including the structural

⁴⁸ See e.g. Commission Decision of 10 January 1995, Case IV/34.279/F3 – Adalat, OJ L 201 (9.8.1996) p. 1, para. 150-152: *"The sale of medicines is influenced by the administrative or purchasing policies adopted in Member States by national health services. For example, some countries take direct or indirect measures to influence prices and there are different levels of reimbursement by the social security system for different categories of medicines. (...) These differences in price-fixing methods and refund arrangements mean that there are wide disparities in pharmaceutical product prices in Member States."*

costs of the production or national turnover when deciding whether to approve or fix a certain price.

Most international manufacturers take advantage of any form of negotiation process to pursue a proactive policy of price differentiation as set out above. As commercial enterprises, they naturally aim to obtain the highest price each market will bear, and so discriminate between countries to reflect differences in the ability and willingness to pay.

While the national health authorities are primarily concerned with the growth in the total cost of the reimbursed medicines' bill under control, they increasingly give commercial freedom to companies to set individual product prices as long as overall budgetary limits are respected.

Consequently, public authorities and multinational firms have concluded various types of agreements in recent years. These may include, for example, the provision of cost-effectiveness studies, volume sales caps, prescribing or advertising restrictions, delayed or immediate price cuts and/or reimbursement de-listings with other, unrelated but ageing products in its portfolio. Price modulation – a mix of price cuts and price increases so that the result is cost neutral – is permitted nearly everywhere.

A unique system of more indirect price control is currently applied in the UK. Indirect price control through profit or rate-of-return regulation considers the manufacturer's contribution to drug development and the economy when determining drug prices. The objective is to ensure that pharmaceutical firms are not making excessive profits, specifically on patent-protected products paid for by public health care systems, but at the same time to reward innovation.

A further point to consider is that price regulation in the different Member States differs also with regard to the kind of price which is negotiated, approved or fixed. The regulated price can be either the manufacturer sales price or the pharmacist sales price. Further, the regulatory systems differ with regard to the trade margins at the different trade levels. Whereas in some countries the wholesaler and the pharmacist margins can be freely determined in others they are not or only to a limited extent negotiable.

For example, in Germany a manufacturer is in principle free to set his standard sales price to the wholesalers for a certain product. However, in deciding about the price he needs to consider that his standard sales price at the same time indirectly determines the pharmacist sales price as this is calculated by law on the basis of his standard sales price plus the maximum wholesale margin for the pharmaceutical plus a certain pharmacist margin whereby both margins are fixed by the German Regulation of Pharmaceutical Prices (Arzneimittelpreisverordnung).⁴⁹ Therefore, the manufacturer can regularly calculate his standard sales price in such a way that the resulting pharmacist sales price matches the reimbursed amount for the pharmaceutical.

However, the obligation to determine a standard sales price does not mean that the manufacturer is not allowed to give any bonuses, cash or other discounts or rebates to the wholesalers. Therefore, especially the granting of natural discounts is a common instrument in Germany but also in other Member States.

(c) *Reimbursement regulation*

Within Europe two systems of reimbursement regulation prevail: systems of positive or negative lists.⁵⁰ In countries with a negative list, medicines that receive marketing approval

⁴⁹ Arzneimittelpreisverordnung vom 14. November 1980 (BGBl. I S. 2147) zuletzt geändert durch das Gesetz vom 14. November 2003, Artikel 24 (BGBl. I S. 2190, 2254).

⁵⁰ Formal details are set out in Council Directive 89/105 of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems; OJ L 40 (11.2.1989) p. 8.

are, by default, reimbursed or have to be placed on a negative list for non-reimbursable medicines. In countries with positive lists, pharmaceutical companies have to apply for the reimbursement status of their product. If this status is granted, the product will be included on a positive list. The principle behind the adoption of such lists is that medicines which are ineffective or are more expensive than equally effective drugs should not be prescribed.

The criteria through which pharmaceutical products are excluded from reimbursement (to be placed on the negative list), and the mechanism by which they are evaluated for reimbursement status (to be placed on the positive list), vary between the Member States and are often vague and not very flexible.

Product lists can be combined with reference pricing or maximum reimbursement levels.⁵¹ This approach aims to create an incentive for both doctors and patients to consider drug prices in decision making, since any cost beyond the reference price must be borne by the patient.

Currently the trend is to link reimbursement decisions to a more economic analysis and in particular to the cost effectiveness of a particular treatment.⁵²

(d) *Patient co-payment*

In almost every Member State patients are expected in principle to contribute financially to the costs of a prescription medicine at the time of their need. This is in addition to their ongoing statutory tax or insurance-based contributions to the system. All countries, however, exempt certain categories of patients from co-payment on socio-economic or medical grounds. Some countries also set a ceiling level of co-payment.

Patient contributions are either a flat rate fee or a proportion of the reimbursement price. In some countries, every patient has to pay a deductible before reimbursement comes in. The co-payment portion often varies with the class of product or the severity and chronic nature of the condition being treated. As a result of these variables there is a marked difference in the average contribution.

(e) *Conclusion*

Member States have found different ways to regulate prices and reimbursement of pharmaceuticals to control expenditures for the national health systems. Nevertheless, all of the systems leave considerable scope for the pharmaceutical producers to influence the price setting, either by direct negotiation processes or indirectly with room for tactical manoeuvre to achieve a profitable price in countries with a cross-country reference system. Additionally, there is scope for competition by natural discounts to influence sales promotions.

2.3 *Dispensing of pharmaceuticals and possibilities to substitute*

In the dispensing process for pharmaceuticals Member States have found another way to introduce cost containment measures. Within the last years they have introduced different regulatory mechanisms for the replacement of a prescribed pharmaceutical by another product. One can broadly differentiate between the possibility of therapeutic and generic substitution and additionally the substitution by parallel distributed products. The possibility

⁵¹ For further details see *Elias Mossialos, Monique Mrazek* Regulating pharmaceutical prices in the European Union in *Elias Mossialos, Monique Mrazek, Tom Walley (Ed.)*, Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 115.

⁵² *Alistair McGuire, Michael Drummond, Frans Rutten*, Reimbursement of pharmaceutical in the European Union in *Elias Mossialos, Monique Mrazek, Tom Walley (Ed.)*, Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 135.

of substitution is usually regulated with regard to the distribution level in which it takes place and can be either an obligatory or a voluntary system.

Annex III sets out the different approaches to substitution in the Member States, from which one can conclude the following tendency:

(a) *Doctors*

Most countries do try not to interfere in the prescription procedure undertaken by the doctors. It is presumed that the doctor knows the patient and the illness better than the regulators. Despite the cost reduction argument most Member States do not have an obligation for doctors to substitute branded products by a generic or to prescribe an active ingredient only.

In Denmark a meditative approach has been chosen. The doctor is under no obligation to prescribe an active ingredient, but obligated to allow substitution by the pharmacist. Italy and other countries on the other hand, impose a cap on doctors' expenditures. This ensures that, in order not to exceed this cap, the doctor will mostly prescribe an active ingredient, allowing pharmacists to sell substitutes.

Nevertheless, for the examined countries it is clear that there is no substitution obligation for doctors.

(b) *Pharmacists*

In a growing number of European countries pharmacists have obtained the right and in some cases even the obligation to substitute the prescription with generics or parallel distributed products as a cost containment measure. Generic substitution is mostly possible when the regulatory authority has defined a list of bioequivalent products. However, as long as there is no generic on the market substitution at the pharmacist level is limited to parallel distributed products. No country allows pharmacists to substitute with therapeutic equivalent products.

The degree of latitude that pharmacists have depends usually on how prescriptions are written. In some countries, the doctor has to endorse the prescription to indicate that substitution can take place in case of that particular patient ('opt-in'). In others, substitution rights can be specifically blocked for individual patients ('opt-out'). For example the 'opt out' system was chosen by Denmark, whereas the 'opt in' system applies to Belgium. In other countries substitution occurs automatically.⁵³

The ECJ already noted in this respect that national rules requiring a pharmacist to dispense only a branded product in response to a prescription may be justified under Article 30 EC on public health protection grounds even where the effect of such rules is to prevent the pharmacist from dispensing a therapeutically equivalent product. Such a provision does not go beyond what is necessary to achieve the objective in view, which is to leave the entire responsibility for the treatment of the patient in the hands of their doctor, who may often prescribe a given medicinal product for psychosomatic reasons.⁵⁴

(c) *Wholesalers*

None of the analysed countries grants the wholesaler the option (or puts them under the obligation) to substitute the pharmaceuticals ordered by the pharmacists or other customers. Wholesalers are therefore limited in their ability to offer alternative products when they are out of stock. This means that wholesalers need to have access to all products to be competitive on the market, as it will be also further explained below.

⁵³ Panos Kanavos, Overview of pharmaceutical pricing and reimbursement regulation in Europe, 2001, p. 20.

⁵⁴ Joined Cases 266/87 and 267/87, *Royal Pharmaceutical Society*, (1989) ECR 1295.

(d) *Conclusion*

The short analysis of the dispensing procedure for pharmaceuticals shows that therapeutic substitution in all Member States is limited to the doctor. He or she represents the only stage in the distribution chain where an effective choice between therapeutically equivalent products can be made. In the majority of Member States, pharmacists then have the possibility of generic substitution or substitution with a parallel distributed product. During the period of patent protection of the branded product the possibilities for pharmacists to substitute are limited to parallel distributed products, if available. None of the Member States allows wholesalers to substitute the orders they receive.

3. Demand for pharmaceuticals – the role of the market participants

The relationship between doctor, patient, pharmacist, wholesaler and health insurance is rather complex: While it is the doctor who decides on the prescription and the pharmacist who dispenses a particular product, it is the health insurance that pays for it in full or in part and it is the patient who actually consumes the medicine.

The individual steps from the doctor's decision for a particular product to delivery and payment play an important role for the market definition and the assessment of anticompetitive behaviour under Article 82 EC. Therefore, the role of the individual market participants shall be briefly considered at this place.

3.1 *Doctors*

When prescribing medicines, the doctors are faced with two decisions: First, whether or not to prescribe a medicine at all, and secondly, the selection of the medicine. In this situation, doctors are bound by their medical evaluation. While within a particular class of medicines there may be some alternatives available, only one of these options may be tolerated and be of benefit for a particular patient. Another patient may only tolerate and benefit from a second product. With the well-recognised individual variability in response to medicines, there is no way of knowing, other than through a systematic approach to each patient's particular circumstances, which product will be of benefit.

Doctors seldom, if ever, consider all possible alternatives of treatment since it is not possible for them to know the details of all marketed products (e.g. up to 40,000 in Germany). Instead, each doctor has his or her personal set of products, approximately 150-200, on which he or she builds up greater knowledge through feedback from patients. The combination of products in this set is, to a considerable extent, influenced by the success of promotional activities of the pharmaceutical industry like visits of medical representatives at doctors practices or advertising (see section 4.5).

When confronted with a specific case, however, only a few of these 150-200 products from the set are reasonable alternatives and will come to the doctor's mind, the so-called evoked set (two to five products). Although in light of cost containment measures the price of a product might be part of the doctor's consideration, it is important to note that in general price considerations are not paramount in a doctor's choice⁵⁵ and can therefore be neglected.

Any competitive assessment of the market behaviour of the pharmaceutical industry the doctor has a key role to play. Since he is the one that primarily decides about the product, his reasoning and decision-making process is an essential parameter in the definition of the market.

⁵⁵ *Howard Morse*, Product market definition in the pharmaceutical industry, 71 *Antitrust L.J.* 2003, p. 633, 938; *Leigh Hancher*, The European Pharmaceutical Market: problems of partial harmonisation, *ELR* 1990, 9.

3.2 *Pharmacist*

Pharmacists act as buffers, filters and interpreters between the doctor and the patient. As well as supplying the medicine, they shield the patient from prescription errors and omissions, and elaborate on illegible, ambiguous or insufficiently detailed instructions.

Pharmacies invariably compete among each other for business in their neighbourhoods. Holding adequate stocks of medicines for which there is a steady or regular demand in the locality is therefore an important factor. However, the range of medicines is so vast, the cost of 'dead stock' so high and storage space so limited that no pharmacy can possibly stock everything. Pharmacies therefore obtain the vast proportion of their stock on an 'as needed' basis from pharmaceutical wholesalers. These in turn are supplied by manufacturers' warehouses or, sometimes, by intermediate contract distributors known as pre-wholesalers. In most of the Member States, pharmacists are moreover obliged to guarantee an immediate supply if a product is not on stock. This means that wholesalers or pre-wholesalers need to deliver a product promptly to the pharmacists when they receive an order.

3.3 *Wholesalers*

Most wholesalers purchase, hold and supply products from a number of different manufacturers in competition with other wholesalers operating in the same national or regional market. This is known as multi-channel distribution. In some Member States wholesalers are obliged by law to hold stock or to guarantee immediate supply. However, in all Member States wholesalers need to comply with the guidelines on good distribution practice as explained in further detail below.

The stocks held in wholesalers' warehouses minimise not only unnecessary transportation, but also stockholding by both manufacturers and retailers. Pharmacies also much prefer dealing with two or three wholesalers, rather than potentially hundreds of manufacturers.

The main competitive elements on which wholesalers compete with each other are simplicity in ordering, speed, reliability and efficiency in delivery, and holding a broad, if not a full range of products in constant supply. There are normally only framework agreements between wholesalers and pharmacies that do not include an obligation to buy. If a product cannot be supplied by the following day at the latest, then the pharmacy would order it from another wholesaler.

3.4 *Health Insurance*

The national health insurance scheme pays for the pharmaceutical product in the end, either by reimbursing the patient or by paying the pharmacists. Although the national systems on reimbursement vary to a certain extent, they have in common that the national authorities and health insurances play a role in negotiating and setting the price for which at the end the product is sold.

From the economic point of view the relevant customers of prescribed medicines are in effect the health insurances⁵⁶ because they influence the price and pay for the product.

3.5 *Patients (Users)*

The patient's economic role in the distribution chain is very limited. They rarely ask about alternative treatments or whether the higher cost of some pharmaceuticals is supported by

⁵⁶ Patrick Rey, *James Venit*, Parallel Trade and pharmaceuticals: a policy in search of itself, ELR 2004, p. 153, 161; *Wolfgang Jaeger*, Die gesetzlichen Krankenkassen als Nachfrager im Wettbewerb, ZWeR 2005, p. 31.

greater therapeutic benefits. Patients are mainly concerned with the outcome of the prescribed therapy and have no incentive to get involved into other considerations.

At the pharmacy, patients normally just pick up the medication prescribed and are rarely allowed to influence which product is dispensed. Only in some circumstances they have a limited choice in the selection of a product when substitution is allowed. In particular when the structure of reimbursement and co-payment does not allow a fixed share of co-payment but is linked to the price of the pharmaceutical, patients might be more sensitive in the product choice. However, this is still the exception and can be neglected for the purpose of this study.

Accordingly, patients are not 'consumers' in the sense that applies in most other markets.⁵⁷

3.6 Conclusion

The individual roles of the market participants in the distribution chain for pharmaceuticals is rather complex and has also implications for the legal assessment of abusive behaviour of pharmaceutical manufacturers under Article 82 EC. However, what is clear is that the decision concerning which pharmaceutical will be used by the patient is regularly taken by the doctor, sometimes influenced by the pharmacist, whereas the wholesaler has to deliver what has been ordered by the pharmacist. The wholesaler has no discretion.

4. The Role of the pharmaceutical industry – innovation as major incentive

Another feature of the pharmaceutical market that needs to be considered in any assessment of anti-competitive behaviour is the role of the pharmaceutical industry itself. This is not only because the pharmaceutical industry is at the centre of the allegations but also because it is using its position on the market to defend its behaviour. One of the main arguments of the pharmaceutical industry to justify the prevention of parallel distribution is the alleged negative impact on R&D budgets of the manufactures.⁵⁸ The pharmaceutical industry claims that parallel distribution reduces the incentive for R&D.

It is not contested that R&D is a critical competitive parameter for pharmaceutical undertakings. However, the discussion sometimes seems to overlook the lack of interconnection between the financial impact of parallel distribution and R&D expenses. Despite parallel distribution (and other impacts on the turnover of pharmaceutical undertakings)⁵⁹ R&D budgets have risen and the largest pharmaceutical companies still register high profits (see **Annex V**).

While the question of innovation is complex and needs a detailed assessment which would go far beyond the aim of this study, some elements in the discussion that seem to be neglected when talking about the negative impacts on R&D shall be pointed out. This chapter further aims to show that the portrayal of parallel distribution as R&D obstructer is highly exaggerated and ultimately wrong.

⁵⁷ Panos Kanavos, Overview of pharmaceutical pricing and reimbursement regulation in Europe, 2001, p. 23.

⁵⁸ See e.g. Patrick Rey, James Venit, Parallel Trade and pharmaceuticals: a policy in search of itself, ELR 2004, 153, 161.

⁵⁹ E.g. generic competition, price regulation and national cost containment measures, etc.

4.1 *Innovation as key driving factor to generate profit*

Any technological progress that leads to the creation of a new product, a reduction in production costs or an increase in the therapeutic value of an existing product⁶⁰ is an important parameter of competition in the pharmaceutical sector.

Typically R&D for a new pharmaceutical product or a different therapeutic indication for an existing product requires substantial investment. The decision to invest in innovation will obviously depend in part on the chances of making sufficient profits to recoup the investment costs. In the pharmaceutical sector the incentive to innovate is mainly market driven. This is because only new products enjoy patent protection and thus have access to certain exclusivity on the pharmaceutical market granting a higher profit margin. Therefore, pharmaceutical undertakings try to achieve protection from competition by obtaining patent protection.⁶¹ Therefore, a successful pharmaceutical manufacturer needs to re-invent its product portfolio approximately every 15 years to remain competitive. Only a constant flow of innovative products can guarantee a strong position in the market and substantial profits in the long run.

However, today R&D strategy focuses mainly on the finding of blockbuster drugs which can generate yearly revenues of more than \$1 billion to also provide funding for future R&D. Companies that depend on the revenue of such blockbuster in particular face problems once patents expire and generics enter the market. Therefore companies must ensure that an appropriate number of potential blockbuster drugs are in the pipeline and constantly continue their R&D approaches.

Added to this, pharmaceutical companies have developed in recent years more and more "me-too" medicines, which are variations of older medicines already on the market with no or limited additional therapeutic value. The strategy behind this is to grab a share of an established, lucrative market by producing something similar to a top selling medicine.⁶² Accordingly, a new pharmaceutical does not necessarily mean that it is in fact an innovative product.⁶³

Nonetheless, one should not overlook that costs for R&D in pharmaceuticals are global joint costs of serving all patients worldwide. That means that the costs are invariant to the number of consumer or countries served at the end.⁶⁴ Accordingly, successful R&D can recoup costs in all states in which it is marketed, the more countries served the higher the recuperation for R&D.

4.2 *Intellectual property rights and regulatory data protection*

Next to trademark rights, patents are the most pertinent intellectual property rights for pharmaceuticals. A patent protects an innovative product or process and aims to encourage research and inventions by ensuring that during the protection period no one else can manufacture the product or use the process. It therefore grants exclusivity for a certain period of time. In Europe patent protection is still granted on a national basis for a period of twenty years maximum.⁶⁵

⁶⁰ Definition from *CRA*, Innovation in the pharmaceutical sector, 2004, p. 44.

⁶¹ The recent Commission decision concerning AstraZeneca's initiatives to delay the market entry of generics shows how patent rights can also be misused (Commission Press releases IP/03/1136 and IP/05/737).

⁶² *Marcia Angell*, The truth about the drug companies: how they deceive us and what to do about it, 2004.

⁶³ *Gerd Glaeske, Katrin Janhsen*, GEK-Arzneimittel-Report 2005, p. 14.

⁶⁴ *Patricia Danzon*, Price discrimination for pharmaceuticals: welfare effects in the US and the EU, *International Journal of Economics of Business*, 1997, 301.

⁶⁵ For the US see: Public Citizen congress watch, R&D myth: the case against the drug industry's R&D "scare card", 2001, p. 16.

Supplementary Protection Certificates (SPC) extend this period of exclusivity to a further maximum of five years after patent protection expires.⁶⁶ The rationale behind SPC is a concession to the pharmaceutical industry extending the exclusivity period because of the time lapses between the patent registration and the final regulatory approval.

Further, data obtained by a pharmaceutical company resulting from pharmaceutical and preclinical trials and information on the assessment of a products quality, safety and efficiency that is necessary for the market authorisation is protected for a period of ten years. This rule ensures that generics can only enter the market after the exclusivity period lapses. The new Directive 2004/27 on medicinal products for human use extends the exclusivity period by another year when the reference holder identifies a significant new indication for its drug.⁶⁷ In this case generics can only enter the market eleven years after the market authorisation was granted.

Accordingly, the pharmaceutical industry has sufficient time to exploit their innovation on an exclusive basis before generics enter the market and enhance competition.

4.3 *State subsidies for R&D*

A further point that is often neglected is that the pharmaceutical industry is supported in their R&D activities by national and international funding and subsidies. Moreover, more and more fundamental R&D that leads to the discovery and development of medicines takes place at universities or is performed by small specialised companies that sell their results to the industry or which are taken over by the industry after having made promising developments.

An internal document of the American National Institutes of Health (NIH) shows, that 55 % of research projects that led to the discovery and development of the top five selling medicines each of which had \$1 billion of sales in 1995 were funded by state subsidies (see **Annex IV**).⁶⁸

This report further suggests that public researchers are doing the work of identifying possible new medicines, while most drug industry R&D spending occurs after companies believe they have a marketable medicine. The NIH report discovered that only 14% of the drug industry's total R&D spending went to basic research, while 38% went to applied research and 48% was spent on product development.

But this example shows that when pharmaceutical industry is arguing with R&D expenses one should scrutinise for each product who exactly carried out the basic or applied research and what kind of financial support was involved at which level of research. It is acceptable to justify high prices by high expenses for R&D but only as long as those costs are actually borne by the manufacturer.⁶⁹

4.4 *No relevant effect of parallel distribution on R&D*

The effect of parallel distribution on R&D budgets has never been established. The allegations of the pharmaceutical industry have been rather rebutted in practice. The

⁶⁶ Regulation 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182 (2.7.1992) p. 1.

⁶⁷ Article 10 para. 1 of Directive 2004/27 of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 (30.4.2004) p. 34.

⁶⁸ NIH contributions to pharmaceutical development: case study analysis of the top-selling drugs, 2000, Appendix C of a report by Public Citizen congress watch, R&D myth: the case against the drug industry's R&D "scare card", 2001.

⁶⁹ For a comprehensive analysis of the market behaviour of the pharmaceutical industry in particular with regard to R&D expenses and pricing see: *Marcia Angell*, The truth about the drug companies: how they deceive us and what to do about it, 2004.

Commission and other national authorities have looked at this question and found no causal relationship between parallel distribution and R&D expenditure.⁷⁰

Moreover, studies on the competitiveness of the pharmaceutical industry show that the reasons for less R&D performance in Europe, if indeed it is less,⁷¹ are structural (e.g. more labour intensive, different structures and strategies in funding, organisational structure and institutional diversity of the research system).⁷² EFPIA members themselves stated that reduced R&D incentives are mainly due to price regulation in Europe.⁷³ In the end, none of these studies could establish a causal link between parallel distribution and R&D budgets or the state of R&D performance.⁷⁴

While there is a general increase of R&D spending worldwide, the pharmaceutical industry continues to register enormous profits (see **Annex V**) at very high levels. Even if the rise in R&D spending might be due to higher R&D costs, it nevertheless proves that the pharmaceutical industry has the capacity to invest in R&D. Moreover, even at times when parallel distribution in the EU/EEA was growing the pharmaceutical industry was able to raise R&D budgets by achieving substantial profits.⁷⁵

Accordingly, a possible impact of parallel distribution on the profits of pharmaceutical manufactures cannot be held equivalent to a possible effect on the R&D budget. It furthermore seems highly speculative that just because of the risk of parallel distribution the industry would have less incentive to undergo R&D activities. They rather delay or withhold the launch of a product in a market to avoid parallel distribution to countries where they can make profits.⁷⁶

The fact that parallel distribution does not have any relevant impact on R&D budgets of pharmaceutical undertakings becomes obvious by comparing the volume of parallel distributed products with the R&D budget of the pharmaceutical industry.

According to recently published estimates for 2004 by EFPIA⁷⁷, the volume of the European pharmaceutical market is at €117 billion (ex-factory prices) or at €180 billion at market value on the pharmacist level. Total R&D expenditures in Europe account for €21.5

⁷⁰ Commission decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001) p. 1, para. 158-160; also the Greek Competition authority could not establish a limitation of R&D expenses in the *Syfait* case, Competition Commission, Decision 193/III/2001 of 3 August 2001, Glaxo Wellcome, GRURInt 2002, 534.

⁷¹ In a hearing conducted by the U.S. Senate Committee for health, education, labour and pensions on 19 April 2005 U.S. Senator Snowe stated that "Research and development spent in Europe by companies is \$26 billion. In America, it's \$32 billion." Similar figures have been quoted by U.S. Senator Stebenow. This shows that the differences in R&D spending between Europe and the US are not as high as the pharmaceutical industry states.

⁷² CRA, Innovation in the pharmaceutical sector, 2004; *Gambardella A., Orsenigo L., Pamolli F.*, Global Competitiveness in Pharmaceuticals a European perspective, 2000; Communication from the Commission, A stronger European-based pharmaceutical Industry for the benefit of the patient – a call for action, COM (2003) 383, p. 18.

⁷³ EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?, 2004, p. 14.

⁷⁴ The same conclusion is drawn by a pharmaceutical industry consultant in *Helena Tobin, Neil Turner*, Parallel Trade 2003 – a concise guide, 2003, p. 78

⁷⁵ See e.g. the conclusion for Germany as an "import state": *Gerd Glaeske, Katrin Janhsen*, GEK-Arzneimittel-Report 2005, p. 18: "Auffällig ist übrigens trotz aller Klagen, dass im Jahre 2003 gegenüber dem Vorjahr zum größten Teil zweistellige Steigerungsraten im Gewinn der Firmen erreicht werden konnten. Von Umsatzeinbußen und schlechten Marktbedingungen kann daher in Deutschland nicht die Rede sein."

⁷⁶ As shown in the example given by EFPIA itself. EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?, 2004, p. 18.

⁷⁷ EFPIA (Ed.), The Pharmaceutical Industry in figures – Update 2005, p.3, available under http://www.efpia.org/6_publ/infigures2005.pdf.

billion or at some 18% of the turnover. This percentage figure comes at the higher end of figures taken from company annual reports, where the ratio of R&D expenditures typically oscillates between 12% and 18% of sales, with variations between years and companies.

However, at the same time the total volume of parallel distributed pharmaceuticals within the EEA (i.e. the EU plus Norway and Iceland; Switzerland does not permit parallel imports of patented medicines) is estimated by EFPIA to be at some €4.3 billion (ex factory prices, 2003).⁷⁸

Parallel distributed pharmaceuticals are all sourced in Europe, at the wholesaler prices of the countries of sourcing. Despite their public complaints, manufacturers are not losing this amount; all they are losing is the margin between the lower and the higher price markets. If one sets that margin at around 30%, even 40%, (an amount which covers average wholesale and pharmacist margins) one arrives at a monetary equivalent for "lost" sales of about €1.3 – 1.7 billion. Given a profitability ranging between 25% and 30% in the pharmaceutical industry and thus amounting to roughly €30 to 40 billion of annual profits achieved in the European market, the impact of parallel distribution is marginal and of no effect if it comes to investment decisions made by the pharmaceutical industry.

Taking these figures as rough estimates - and they do not pretend to be more - it nevertheless becomes clear that with the volumes at stake, parallel distribution of pharmaceuticals in Europe is not the great threat capable of undermining the R&D capacity of the European pharmaceutical industry.

4.5 *Brand loyalty*

In the absence of price competition, pharmaceutical companies promote their products on the basis of their qualities. The industry spends considerable amounts of money to build up brand loyalty with consumers and health professionals.⁷⁹ Brand loyalty is primarily used to protect the products from new market entries after the patent expires.⁸⁰

An estimated 90% of promotional expenditure by industry, totalling almost €5 billion in 2003 in the EU's five largest national markets alone (see **Annex VI** and **Annex V**), is spent on sales promotions.

There is also considerable spending on sponsored articles, seeding trials, assistance with research expenses, invitations to attend conferences (both at home and overseas), medical education, disease awareness campaigns, electronic detailing, direct mail, brochures/leave pieces, free samples, gifts and incentives, hospitality, video and audio cassettes, and medical television. Although doctors often claim that their final decision to adopt a new medicine is not influenced by commercial pressures, it has been shown that industry-supported activities do influence decisions whether or not to prescribe a new medicine.

Brand loyalty can therefore lead to consistent market shares even after patent expiry. Normally the entry by generic products leads to a significant price drop. However, brand loyalty and price regulation allow that prices and market shares do not vary substantially after a patent expires.⁸¹

⁷⁸ EFPIA (Ed.), *The Pharmaceutical Industry in figures – Update 2005*, p. 4, available under http://www.efpia.org/6_publ/infigures2005.pdf.

⁷⁹ *Stephen Koen, Fiona Schaeffer*, *Parallel Imports of Pharmaceutical Products: a new realism, or back to basics*, ECLR 1997, 123, 124; Public Citizen congress watch, *R&D myth: the case against the drug industry's R&D "scare card"*, 2001, p. 13.

⁸⁰ *Leigh Hancher*, *The European Pharmaceutical Market: problems of partial harmonisation*, ELR 1990, 9.

⁸¹ *Gambardella A., Orsenigo L., Pamolli F.*, *Global Competitiveness in Pharmaceuticals a European perspective*, 2000, p. 9 and 60.

4.6 Conclusion

Parallel distribution has only a marginal impact on profits in the pharmaceutical industry and the sector's profitability nevertheless continues to grow. The incentive for R&D is market-driven. Calculations on the return of investment in innovation are rather complex and need to consider various factors, such as national price regulations and the duration of exclusivity. The effect of parallel distribution within this calculation is limited, if not non-existent.

The possibility of parallel distribution of a product simply adds to the competitive environment a pharmaceutical producer has to face. In isolation, parallel distribution will not change the incentives of the pharmaceutical industry to invest in R&D.

Furthermore, as the Commission has set out in detail in the *GlaxoWellcome Spain* decision, a company can react to a decline in profits by parallel distribution in reducing other cost-intensive items like marketing costs instead of R&D investments.⁸²

5. Legal Framework for distribution of pharmaceuticals

A further point that is usually neglected in the discussion about parallel distribution of pharmaceuticals is that it is also subject to regulation. Furthermore, wholesalers have to comply with a public service obligation which has also an impact on their ability to engage in parallel distribution.

Therefore, unlike for other goods, the inter-community distribution of pharmaceuticals cannot be simplified to a pure trade and transport activity. While exporters are authorised wholesalers, importers qualify both as authorised wholesalers and as manufacturers. For their manufacturing activities they are subject to the same stringent rules and inspections as brand manufacturers.

5.1 General Rules and Regulations

In general, wholesale distribution of medicines is regulated by Directive 2001/83 (as amended by Directive 2004/27).⁸³ All wholesalers are required to hold a wholesale dealing authorisation, to purchase medicines covered by a marketing authorisation granted under Regulation 726/2004⁸⁴ only from authorised manufacturers or other authorised wholesalers, and sell such medicines only to authorised pharmacists or other authorised wholesalers.

Wholesalers that import pharmaceutical products into other Member States, however, must meet further requirements. First, they must qualify for GMP (good manufacturing practice in pharmaceuticals) status. They must obtain a national authorisation for each product they want to import. This might be done by a reference to the marketing authorisation of the original manufacturer.⁸⁵ Parallel distributors have to show that the imported product is identical to the version existing on the national market. They usually must then repackage the product, replace labels and add new notices in the language of

⁸² Commission Decision of 8 May 2001, Case IV/36.957/F3 – *Glaxo Wellcome*, OJ L 302 (17.11.2001) p. 1, para. 157.

⁸³ Directive 2004/27 of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 (30.4.2004) p. 34.

⁸⁴ Regulation 726/2004 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, OJ L 136 (30.4.2004) p. 1.

⁸⁵ See e.g. ECJ Case 16/74, *Centrafarm v. Winthrop*, (1974) ECR 1183.

the importing country.⁸⁶ However, parallel distributed products are not changed in their substance and they are of no risk to patients' safety just because they are imported.⁸⁷

No parallel distributed product may be marketed until specific authorisation for it is given by the responsible regulatory authority. This authorisation is specific to the product, dosage form, strength, pack size, country of origin, country of destination, and the name of the parallel importer and the re-packager (if different). Therefore, for each dosage form, strength and source country a separate application is necessary.

Time for authorisation in some countries (e.g. Denmark, Germany, Sweden or the UK) take an average of several months and can sometimes even exceed one year. Authorisations are published in the country's official journal and are valid for five years before renewal is necessary.⁸⁸ The regulatory authority or the parallel distributors will inform the marketing authorisation holder or the trade mark holder in the country of destination that a parallel distribution approval has been granted on his territory.

EMA has also had a parallel distribution scheme since 1998 for products approved centrally pursuant to Regulation 726/2004. Notifications have to be made on a special form, accompanied by a fee and a sample of the parallel-distributed product. Though a notice allowing parallel distribution is supposed to be issued by EMA in 35 days (5 days validation, 30 days processing) from receipt of the notification, in practice the delay averages 4-6 months. Similar to national procedures, a new notification has to be filed if the source country changes and has not been included in the initial list of source countries.

5.2 *Public service obligation*

On the European level, Directive 2001/83⁸⁹ introduced, for the first time in EU law, a 'public service obligation', which is defined in Article 1(18) of the directive as the obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short period of time over the whole of the area in question.

Directive 2004/27⁹⁰ amending Directive 2001/83⁹¹ which has to be implemented by the Member States until 30 October 2005 will add a new Article 81 that reads as follows:

"The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a member state shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the member state in question are covered."

⁸⁶ For details see: Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, COM (2003) 839.

⁸⁷ Allegations that parallel distribution would risk consumer safety and encourage counterfeit products are unproved. Rather the opposite can be shown, see e.g. answer of the German government on a parliamentary request, regarding the role of imported pharmaceuticals in the pharmaceutical supply, BT-Drs. 15/1431, p.7; press release of the EAEPD of 8 July 2004 at <http://www.eaepd.org>.

⁸⁸ Article 24 Directive 2001/83 of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 (28.11.2001) p. 67.

⁸⁹ Directive 2001/83 of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 (28.11.2001) p. 67.

⁹⁰ Directive 2004/27 of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 (30.4.2004) p. 34.

⁹¹ Directive 2001/83 of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 (28.11.2001) p. 67.

This article therefore extends the existing service obligation for wholesalers to authorisation holders. The motion for this amendment had been expressed by the European Parliament's industry committee as follows:

"There is evidence to suggest that manufacturers are withholding and/or restricting supply of prescription medicines to wholesalers in Member States. This is against the principle of the single, free internal market and is causing unacceptable disruption of the supply of essential medicines to patients."⁹²

While it is still not clear how this obligation will be interpreted in practice and what kind of responsibilities manufacturers will face,⁹³ the obligations for wholesalers have already been defined.

The European Commission published in 1994 its 'Guidelines on good distribution practice'.⁹⁴ Pursuant to these guidelines, wholesalers are required to have a quality system that

"should ensure the right products are delivered to the right addressee within a satisfactory time period".

Furthermore, the guidelines provide that:

"in case of emergency, wholesalers should be in a position to supply immediately the medicinal products that they regularly supply to persons entitled to supply the products to the public".

In addition the public service obligation for pharmaceutical wholesalers is already found in the national laws of the majority of the EU Member States. It is reflected by the obligation to hold stock of a particular group of products for emergency cases in some countries or to have nearly a full range of products available in others.

Countries that do not have an obligation to hold stock for wholesalers oblige the pharmacists to hold a sufficient stock to meet the demand. This in turn forces the wholesalers to have a full line of products available to secure that pharmacies can meet their obligation at any time. For more details see **Annex VII**.

The public service obligation is thus an essential consideration for the commercial activities of the wholesalers. It governs their behaviour in the distribution of pharmaceuticals.

5.3 Conclusion

Unlike numerous other goods the distribution of pharmaceuticals is regulated and can only be practiced under certain conditions. Within the regulatory framework for the distribution of pharmaceuticals there are specific rules influencing and regulating the cross-border trade of medicines. These parameters define obligations for wholesalers practicing parallel distribution in the import and export countries.

In the country of export for any given medicine, it is mainly the public service obligation that determines the framework of activity of the wholesalers while in the import country

⁹² Opinion of the Committee on Industry, External Trade, Research and Energy on the proposal for Directive amending Directive 2001/83 on the Community code relating to medicinal products for human use, A5-0340/2002, p. 114.

⁹³ See e.g. *Ulrich M Gassner*, How recent changes in EU competition and pharmaceutical law will affect parallel trade, RAJ Pharma 2004, p. 655, who interprets it as "*responsibility for a demand-oriented, fair and continues supply of national market[s]*".

⁹⁴ Guidelines on good distribution practice of medicinal products for human use, OJ C 63 (1.3.1994) p. 4. Following Article 80 (g) Directive 2001/83 wholesalers must comply with those guidelines.

distributors have additional obligations to fulfil for authorising imported pharmaceuticals and for placing a product on the market.

6. The Impact of parallel distribution on competition and consumer benefits

The question as to whether or not parallel distribution benefits the consumers and the national health care systems has long been hotly debated. The pharmaceutical industry is quick to use the argument that there are no benefits to provide justification for their anti-competitive activities on the market.

Obviously, the pharmaceutical industry argues that parallel distribution does not benefit anyone else than the parallel distributors.⁹⁵ A study conducted by the London School of Economics on behalf of Johnson & Johnson in 2003 also came to the conclusion that the main beneficiaries of parallel distribution are the pharmacists and parallel distributors and that there are no measurable benefits for the consumers.⁹⁶

However, this study is based on a number of assumptions and facts that weaken the significance of its conclusions.⁹⁷ For instance, the samples of pharmaceuticals used were only to a limited extent subject to parallel distribution during the period under review. Therefore, it is obvious that savings were limited as well. Moreover, many of the importers' costs (e.g. for quality controls, repackaging, regulatory obligations) were not included in the calculations. Finally, the prices used were pharmacy purchase prices instead of ex-factory prices without taking into account the discounts and rebates usually granted. The picture drawn by this study is therefore highly questionable.

This is certainly not the place to go into a detailed analysis about the benefits of parallel distribution. However, since it is still one of the main arguments used to justify anticompetitive behaviour⁹⁸ it seems necessary to at least set out some explanatory notes.

6.1 Integrative factor of Parallel distribution

Parallel distribution in general encourages integration since it forces the market participants to deal with the different applicable market mechanisms. This is also true for the parallel distribution of pharmaceuticals. The Commission acknowledges that:

"parallel trade must [...] be seen as an important driving force for market integration and, consequently, for achieving the Single Market."⁹⁹

The integrative effect is often denied by the industry arguing that by now parallel distribution has not resulted in a harmonisation of prices. This argument is, however, misleading. First of all it is not in the interest of the pharmaceutical industry to have a single European price since they promote price discrimination. And second, the pharmaceutical industry implements its price discrimination strategy wherever possible. Integration is further not limited to price harmonisation. Parallel distribution of pharmaceuticals also leads to increased competition among different national health regulation schemes in Europe that pushed the authorities toward more integration and the

⁹⁵ EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?, 2004, p. 17 and 61; *Patricia Danzon*, Price discrimination for pharmaceuticals: welfare effects in the US and the EU, *International Journal of Economics of Business*, 1997, p. 301.

⁹⁶ *Panos Kanavos/Joan Costa-i-Font/Shery Merkur/Marin Gemmill*, The economic impact of pharmaceutical parallel trade in European Union Member States: a stakeholder analysis, 2004, p. 15.

⁹⁷ See e.g. *Peter West/James Mahon*, A commentary on the LSE report, 2004; Press release of the EAEPD of 25 March 2004 at www.eaepd.org.

⁹⁸ See e.g. also Opinion of Advocate General Jacobs from 28 October 2004 in C-50/03 *Syfait*, para. 96.

⁹⁹ Commission Communication on the Single Market in Pharmaceuticals, COM (98) 588, p. 4.

acknowledgement of best practices.¹⁰⁰ Additionally, the possibility of parallel distribution leads to more cross-border competition in the wholesaler sector and on the pharmacy level.

6.2 *Direct savings for consumers*

A study conducted by the York Health Economics Consortium in May 2003 (York Study) came to the conclusion that parallel distribution results in considerable direct and indirect savings.¹⁰¹ The study was carried out for the five EU countries where most parallel imports take place.¹⁰² For 2002 the study concluded savings for those five countries of a total of € 631 million. The direct savings achieved were passed mainly to the respective health insurance systems, but also to patients insofar as there is co-payment involved.¹⁰³ For example, in Germany in the year 2002 over €10 million was saved on oral contraceptives.¹⁰⁴ As these costs are borne mainly by the consumers themselves, they benefited directly from the savings.¹⁰⁵ Also the Commission noted that:

*"Patients benefit directly from parallel trade either when they have to pay the full amount of the purchase price themselves or when reimbursement is only partial and is expressed as a percentage of the actual purchase price (in contrast with a flat fee)."*¹⁰⁶

Within the last years national governments and health providers especially in the importing countries have introduced measures that provide incentives for the sale of parallel distributed products to gain further savings. For instance in Germany pharmacists are obliged to substitute with a parallel distributed product if they are 15% or more than €15 cheaper than the original product. In addition, they need to fulfil a sales quota of 5% of parallel distributed pharmaceuticals. In Denmark pharmacists have an obligation to dispense the cheapest product in a substitution group unless the price differences are modest. This shows that the national governments have a substantial interest in parallel distribution and that savings generated through parallel distributed products are part of their cost calculation.

6.3 *Indirect savings*

Parallel distribution also creates increased price competition.¹⁰⁷ Indirectly, parallel distribution or the "threat" of parallel distribution leads to more competitive prices that are negotiated by the governments in the importing states, indirectly benefiting all buyers.¹⁰⁸ In

¹⁰⁰ Christian Koenig, Christina Engelmann, Parallel Trade Restrictions in the Pharmaceutical Sector on the Test Stand of Art. 82 EC: Commentary on the Opinion of Advocate General Jacobs in the Case Syfait/GlaxoSmithKline, ECLR 2005, p. 338, 341.

¹⁰¹ Peter West/James Mahon, Benefits to Payers and Patients from Parallel Trade, study by the York Health Economics Consortium (YHEC) commissioned by the European Association of Euro-Pharmaceutical Companies, May 2003 (York Study).

¹⁰² Denmark, Germany, Great Britain, the Netherlands and Sweden.

¹⁰³ York Study p. 67, details regarding the individual states, p. 7-66.

¹⁰⁴ York Study p. 51.

¹⁰⁵ For the possible substantial savings for the contraceptive pill see also the press release by the Scientific Institute of the AOK (WIdO) of 10 October 2002, Imported drugs can save € 450 million per year; <http://www.wido.de>.

¹⁰⁶ Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001) p. 1, para. 183.

¹⁰⁷ Commission Decision of 13 July 1987, Case 87/409/EWG – Sandoz, OJ L 222 (10.8.1987) p. 28 para. 6.

¹⁰⁸ A study by the University of Kuopio modelled a hypothetical case in which manufacturers decided to react to lower parallel distribution prices. This resulted in potential savings of between € 5.2 million and € 17.3 million: *Linnosmaa/Karhunen/Vohlonen*, Parallel importation of pharmaceuticals in Finland: effects on markets and expenditures, Pharm Dev Regul 2003:1(1):67-74. Another study conducted by the Research Institute of Industrial Economics, Stockholm, came to the conclusion that prices of products subject to parallel distribution after Sweden joined the EU fell approximately 4 % relative to the prices of products

fact, as long as pharmaceuticals are protected by intellectual property rights parallel distributed products are the only source of competition.

"Parallel trade also generates indirect savings by creating competition, where otherwise there is none, and thus forcing pharmaceutical manufacturers to reduce the prices of domestically sourced products. These indirect savings are difficult to quantify but they could be larger than the direct savings."¹⁰⁹

Moreover, indirect savings can be assumed also in the exporting states whose healthcare systems are de facto subsidised by parallel-distribution.¹¹⁰ Additionally, the possibility of parallel distribution leads to more efficient and economical distribution systems in the exporting countries which again provide indirect benefits to patients there.¹¹¹

6.4 Conclusion

Parallel distribution of pharmaceuticals is an accepted commercial practice that is based on the principle of free trade within the internal market of the EU. It cannot be reduced to a simple arbitrage activity since the cross border trade with pharmaceuticals is subject to high regulatory safety standards and public service obligations. Governments in the importing states support the import of cheaper drugs since their social systems and consumers can benefit from lower costs. Exporting countries will not prevent exports as long as wholesalers comply with their public service obligations since they indirectly benefit as well from the cross-border trade.

7. Conclusion

The pharmaceutical market is characterized by certain peculiarities that need to be considered in the legal analysis of anti-competitive behaviour of pharmaceutical undertakings.

Primarily it is the asymmetrical structure of demand and supply that characterises the pharmaceutical market. Unlike in a normal demand and supply chain the decision for and the sale of a pharmaceutical product involves different decision-makers with different margins of action. The final consumer - the patient - plays only a marginal role in the decision making procedure. It is mainly the doctor who decides about the product and the government that pays the bill, that are of importance in the demand analysis.

It is further to note that only doctors can effectively choose between therapeutic equivalent products. Pharmacists are limited to generic substitution or substitution by a parallel distributed product when they receive a prescription. This choice is limited to the latter possibility as long as no generics are available. Moreover, wholesalers cannot substitute pharmaceuticals at all. This structure restricts the individual participants of the supply chain in their commercial activities to an important extent since they are not as flexible as other wholesalers or retailers to supply alternative goods if they are out of stock.

Second, it is the product itself that influences the market structure. Pharmaceuticals are in many cases vitally important and national governments profess to guarantee access to safe and effective medicines. In order to ensure that expenditure for pharmaceuticals do not become excessive Member States tend to regulate the price setting and the reimbursement levels. This does, however, not affect the ability of the pharmaceutical

not subject to parallel trade: *Mattias Ganslandt, Keith E. Markus, Parallel imports and the pricing of pharmaceutical products: evidence from the European Union, 2004.*

¹⁰⁹ York Study p. iii

¹¹⁰ York Study p. 5. *Govin Permanand, Christa Altenstetter, The politics of pharmaceuticals in the European Union in Monique Mrazek, Tom Walley (Ed.), Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 46.*

¹¹¹ See also *J Baker, Parallel importing strategies, Scrip Report, 2000, p. 20.*

industry to take decisive influence in the price regulation process. There is enough scope for the industry to achieve acceptable product prices in the different national markets so that they do not sell their products at loss. On the contrary, the pharmaceutical industry is one of the most profitable industries in the world.

Last but not least the pharmaceutical market is characterised by a high level of innovation and large investments in R&D. However, it is not only the industry itself which has to bear the costs for R&D. The pharmaceutical industry is profiting from considerable public financial support and research undertaken by public researchers. It can further exploit the results of R&D exclusively for the period of patent protection.

Parallel distribution of pharmaceuticals, on the other hand, has no measurable, negative influence on R&D budgets. It is an accepted commercial practice that is based on the principle of free movement of goods and can lead to more competition in the wholesaler sector. Parallel distribution of pharmaceuticals allows considerable direct and indirect savings for consumers and national health systems in both, import and export states.

III THE APPLICATION OF ARTICLE 82 EC

1. Market definition

1.1 Introduction

A prerequisite for any assessment under Article 82 EC is the identification of the relevant market on which the undertaking may have a dominant position. In general, the market definition focuses on two issues: the product and the geographic market.

The relevant product market has been described as:

"the market for all the products and/or services in question which are regarded as interchangeable, or substitutable, by the consumer by reason of their use, price and characteristics".¹¹²

The relevant geographic market, on the other hand, is defined in the relevant notice as:

"the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those area."¹¹³

Therefore, the exercise of market definition consists of identifying effective alternative sources of supply for the consumer. Without repeating in detail the existing case law on market definition and the well established principles¹¹⁴ one can summarise that a general analysis will have to take into account the economic context, including the objective characteristics of the product; the degree of inter-changeability between the products,¹¹⁵ having regard to their relative prices and intended use;¹¹⁶ the competitive conditions; the structure of supply and demand;¹¹⁷ and the attitudes of consumers and users. Neither of these points is exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case depends on its own facts and the following exercise can only set the frame in which a market analysis in the pharmaceutical sector takes place.

The usual instrument which the Commission uses to find alternative sources of supply for the consumer - the hypothetical price increase test based on assumption that the reaction of consumers to a change in price shows whether there are any suitable alternatives¹¹⁸ - cannot be applied in the pharmaceutical sector (see section 1.3.lit.(a)).

So far, there is no case law on market definition in the pharmaceutical sector with regard to Article 82 EC.¹¹⁹ However, the following section will show that there are a number of EC merger decisions and Article 81 EC cases in which the market definition in the pharmaceutical sector has been discussed (see section 1.3 lit.(b)). The question remains

¹¹² Commission Notice on the definition of the relevant market, OJ C 372 (9.12.1997) p. 3, para. 7.

¹¹³ Commission Notice on the definition of the relevant market, OJ C 372 (9.12.1997) p. 3, para. 8.

¹¹⁴ See e.g. *Bellamy & Child*, European Community Law of Competition, 2001, para. 9-011 until 9-064; *Faull & Nikpay*, The EC Law of Competition, 1999, chapter 1.

¹¹⁵ Case 85/76, *Hoffmann-La Roche*, (1979) ECR 461, para. 28.

¹¹⁶ Case 27/76, *United Brands*, (1978) ECR 207, para. 30 et seq.

¹¹⁷ Case 322/81, *Michelin*, (1983) ECR 3461, para. 37.

¹¹⁸ Commission Notice on the definition of the relevant market, OJ C 372 (9.12.1997) p. 3, para. 17.

¹¹⁹ There is one recent decision concerning AstraZeneca's initiatives to delay the market entry of generics, which is however not yet published (Commission Press releases IP/03/1136 and IP/05/737).

whether the method used to describe a market in a merger control procedure can be equally applied in an Article 82 EC case.

Similarly, national competition authorities and courts (including the US authorities) have been reluctant to establish standard criteria for a market analysis in the pharmaceutical sector. There are however a few national decisions which could offer further guidance for the interpretation of the pharmaceutical market (see section 1.3. lit.(c)).

A number of criteria can be derived from the decisions of the Commission, national authorities and the courts, which have repeatedly influenced the assessment of market definition in the pharmaceutical sector (see section 1.3 lit.(d)). These criteria set the general framework for the market definition for pharmaceuticals.

However, as will be proven hereinafter, nearly all decisions until now have ignored one particularity of the pharmaceutical market: the distribution structure and the demand process. The special mechanisms working in the pharmaceutical market, which are explained above, must be taken into consideration for the market definition, and in the end lead to the conclusion that the market, in the vertical relationship between manufacturer and wholesaler, needs to be reduced to one product (see section 1.4).

1.2 *No separate product market for pharmaceutical products capable of parallel distribution*

Before looking into detail of possible criteria for the definition of the product market one particular approach on market definition supported by the pharmaceutical industry has to be commented separately.

It has been suggested by some commentators and industry actors that there is a separate product market for all pharmaceutical products capable of being parallel distributed profitably.¹²⁰ This theory is based on the following assumption: exporters have no public service obligation and traders and wholesalers are not concerned by the therapeutic effect of a drug when they trade pharmaceutical products but only on price differences.¹²¹ Therefore, it is considered that medicines with the same potential profit margin could be held substitutes. As it will be shown below not only are the assumptions on which this theory is based incorrect but the theory itself ignores basic principles of the common market and competition policy.

(a) *Public service obligation for wholesalers*

First of all, the theory ignores the market mechanisms that govern the distribution chain. As seen above under European law all wholesalers have a public service obligation (see chapter II, section 5.2). As it will be shown in detail below the public service obligation, in connection with the specific structure of supply and demand in the pharmaceutical sector, plays not only a crucial role as concerns the market definition but also with regard to the assessment of dominance.

Due to the obligation to keep sufficient stock of pharmaceuticals at all times to guarantee a supply of the population, wholesalers constantly have to replenish their stocks so as to warrant a comprehensive supply. However, wholesalers will only be able to meet that obligation if sufficient supplies are made available to them by the manufacturers. The statutory obligation to keep sufficient stocks puts wholesalers in a dilemma, making them dependent on sufficient supplies by the manufacturers. The obligation to meet the demand

¹²⁰ *Frédéric Jenny*, Pharmaceuticals Competition and Free Movement of Goods, EU Competition Law & Policy, 2002, p. 82; *EFPIA*, Article 82 EC: Can it be applied to control sales by pharmaceutical wholesalers?, 2004, p. 31.

¹²¹ *Frédéric Jenny*, Pharmaceuticals Competition and Free Movement of Goods, EU Competition Law & Policy, 2002, p. 82; *EFPIA*, Article 82 EC: Can it be applied to control sales by pharmaceutical wholesalers?, 2004, p. 31.

of the pharmacists leads to an inflexible demand of the wholesalers themselves and therefore to a relative dependence on the manufacturers.

(b) *Demand side substitutability defined by the end-consumer*

Furthermore, the theory of a separate product market for all products capable of parallel distribution is mainly based on the assumption that the wholesaler is the consumer whose demand and possibilities to switch are decisive for the analysis of demand-side substitutability. This assumption, however, ignores the fact that the demand of pharmaceutical wholesalers and traders is determined by the demand of their customers (e.g. hospitals, pharmacies and other wholesalers), whose demand is itself directly influenced by the prescription of a particular product by doctors.

Defining the market in a vertical relationship always leads to the question on which level the demand is defined, e.g. the end-consumer, the retailers or the wholesalers and intermediaries. One has to differentiate between vertical chains - where on the intermediary level changes to the product take place - and chains where the supply of a product is the central activity. In the first group the direct buyer's preferences are in most cases decisive for defining the market while:

*"[i]n the case of distribution of final goods, what are substitutes for the direct buyers will normally be influenced or determined by the preferences of the final consumers. A distributor, as reseller, cannot ignore the preferences of final consumers when he purchases final goods."*¹²²

Since pharmaceutical wholesalers are pure distributors that do not buy intermediate products but final goods for resale, one cannot ignore that their demand is strongly influenced by the demand of the final consumers. In addition, the peculiarities of the supply chain, as it will be shown below, need to be considered (see section 1.4).

There is nothing to suggest that these considerations do not equally apply to products that are exported. On the contrary, if there is no demand from the end-consumer, an importer will not buy a particular product just because there is a price difference that could make it attractive for parallel distribution.

(c) *Conclusion*

The approach to define a separate market for all pharmaceuticals capable of profitable parallel distribution must be rejected as unfounded. The market definition cannot be solely dependent on the location where the product is distributed.

On the contrary the evaluation of the market must, in the first instance, focus solely on the manufacturer's conduct in view of a specific product. The market definition in the case of distribution of final goods has to focus on the product and its substitutability defined by the end-consumer.¹²³ The fact that the same product is parallel distributed might, at the utmost, come into play in the justification of the objectionable conduct, but not in the market definition.

1.3 *Methods to define a specific product market*

The inter-changeability or substitutability between a given number and a group of products is an important element for defining the relevant market, but not the only one. There are a number of indicators or criteria that should be applied. These criteria need to be considered with regard to the pharmaceutical market. Furthermore, the structure of the market and the relevant rules that apply to it have a particular influence on the product

¹²² Commission Notice, Guidelines on vertical restraints, OJ C 291 (13.10.2000) p. 1, para. 91.

¹²³ With the same conclusion: *Erwin Krapf, Barbara Lange*, Staatliche Intervention, duale Preissysteme und europäisches Kartellrecht, PharmR, 2005, p. 321, 322.

market definition. Accordingly, a market definition in the cases at stake will need to reflect on the structure and the regulatory framework of the pharmaceutical market.

(a) *Hypothetical price increase test*

The hypothetical price increase test is used to determine the degree of substitutability focusing on consumer reactions on small, permanent changes in price.¹²⁴The common understanding is that the hypothetical price increase test cannot be applied to the evaluation of markets in the pharmaceutical sector.

The final consumers for pharmaceuticals are not price sensitive because – in Europe at least - it is the health security system that is financing the products with its reimbursement policy. It is often the case that the final consumers do not even know the price of a pharmaceutical they receive. A price increase would therefore not necessarily lead to a reaction from the patients. However, if one assumes that the health insurance is the actual buyer and therefore the consumer in the economic sense one could assess the reaction of the health insurance to a possible price increase. This would presume though that the health insurance chooses the product and would be able to switch as a reaction to a price increase. But this is not the case. Therefore, the only remaining alternative would be to turn to the reaction of the doctor. For the doctors prescribing a particular medicine the indication, effectiveness and appropriateness of the pharmaceutical in question for his patient will play the pre-eminent role. The price, however, will play a limited role in his decision making process, if at all. Although in light of national cost containment measures doctors might today reflect more on the price of a particular pharmaceutical than in the past, or indeed be encouraged to do so, the price is and will never be the determining factor in the decision of the doctor.

Accordingly, the application of the hypothetical price increase test in the pharmaceutical sector is excluded, at least for all products that are subject to the specific circumstances of prescribing rules and reimbursement mechanisms.

(b) *The Commission approach - ATC classification*

(i) *ATC classification*

The WHO Anatomical Therapeutic Chemical Classification system (ATC) has been used in several pharmaceutical merger cases by the European Commission for market definition purposes. It groups pharmaceutical products according to the organ or system in which they act and their chemical, pharmacological and therapeutic properties.¹²⁵ In the absence of data for the ATC classification and in a few other cases the Commission alternatively relied on the ATC classification from the European Pharmaceuticals Manufacturers Association (EPHMA) that leads to similar results.¹²⁶

The ATC system differentiates between five different levels, starting with the anatomical group, followed by the therapeutic group and three subgroups. In its merger cases, the Commission has mainly used ATC-3 (the third level) to establish a market definition, which is the therapeutic/pharmacological sub-group:¹²⁷

¹²⁴ Commission Notice on the definition of the relevant market, OJ C 372 (9.12.1997) p. 3, para. 17.

¹²⁵ For further details see <http://www.whocc.no/atcddd/>.

¹²⁶ Commission Decision of 16 July 1996, Case IV/M.737 – Ciba-Geigy/Sandoz; Commission Decision of 8 May 2000, Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham; Commission Decision of 27 February 2003, Case COMP/M.2922 – Pfizer/Pharmacia.

¹²⁷ Commission Decision of 29 April 1993, Case IV/M.323 – Procordia/Erbamont; Commission Decision of 6 September 1994, Case IV/M.464 – BMSC/UPSA; Commission Decision of 13 September 1996, Case IV/M.781 – Schering/Gehe-Jenapharm; Commission Decision of 22 May 2000, Case COMP/M.1878 – Pfizer/Warner-Lambert.

"The third level classes of the ATC classification provide a grouping of medicines according to their therapeutic properties, that is, their intended use, and therefore may be accepted as an operational market definition."¹²⁸

However, the Commission admitted that the third level is not sufficient in all cases to define the relevant market, in particular when the pharmaceuticals have clearly different therapeutic indications.¹²⁹

(ii) *No equal application of ATC in merger control cases and Article 82 EC cases*

The ATC approach cannot necessarily be used in the same way to define the market in Article 82 EC cases as it is used in merger control cases. The reason for this is twofold: First, the market definition in a merger assessment pursues a different aim than in antitrust cases. Each market definition has to consider the aim of the respective legal provision.¹³⁰ Second, the ATC classification alone is inappropriate to define substitutability.

In merger control cases the issue analysed by the authorities is whether horizontal concentration will in future lead to a reduction in the competitive constraints on the merged entity.¹³¹ It rather aims to prevent the establishment of a dominant undertaking in the future than to control the behaviour of a dominant undertaking as such. Therefore, market definition in merger control is a dynamic analysis that combines current market information with a prognosis of the future development.¹³²

In contrast, the market definition in an Article 82 EC case aims to assess the effects of a particular behaviour in the past and present. It is therefore a retrospective analysis of the market that is solely based on market information at the time of the anticompetitive behaviour¹³³ and, thus, more stringent than the one in merger control cases.

Furthermore, the analysis of anticompetitive behaviour in vertical relations needs to take into account additional considerations when defining the market, as it has been explained by the Commission in the Guidelines on vertical restraints.¹³⁴

It is established case law that the market must always be defined in any particular case by reference to the facts prevailing at the time and not by reference to precedents.¹³⁵ Therefore, an Article 82 EC analysis of the market will not necessarily follow precedents in merger control or other antitrust cases.¹³⁶ As a tendency the relevant markets in Article 82 cases are narrower than in merger cases.

Furthermore, in addition to a different approach on market definition induced by different concepts of the merger control regulation and of Article 82 EC, it is debatable whether the

¹²⁸ Commission Decision of 20 June 1994, Case IV/M.457 – La Roche/Syntex; Commission Decision of 28 February 1995, Case IV/M.555 – Glaxo/Wellcome; Commission Decision of 16 July 1996, Case IV/M.737 – Ciba-Geigy/Sandoz.

¹²⁹ Commission Decision of 20 June 1994, Case IV/M.457 – La Roche/Syntex; Commission Decision of 3 April 1995, Case IV/M.495 – Behringwerke AG/Armour Pharmaceutical Co.; Commission Decision of 29 April 1993 Case IV/M.323 – Procordia/Erbamont; e.g. ATC 4 in Commission Decision of 27 February 2003, Case COMP/M.2922 – Pfizer/Pharmacia.

¹³⁰ Helmuth Schröter u. Schröter/Jacobs/Mederer Kommentar zum Europäischen Wettbewerbsrecht, 2005, Artikel 82, para. 126; Van Damme, La politique de la concurrence dans la CEE, para. 403.

¹³¹ Dermot Glynn, Article 82 and price discrimination in patented pharmaceuticals: the economics, ECLR 2005, p. 135.

¹³² Case C-68/94, *SCPA and EMC v. Commission*, (1998) ECR I-1375, para. 180.

¹³³ Joined Cases 40 et al./73, *Suiker Unie*, (1975) ECR 1663, para. 450.

¹³⁴ Commission Notice, Guidelines on vertical restraints, OJ C 291 (13.10.2000) p. 1, para. 88 et seq.

¹³⁵ Joined Cases T-125/97 and T-127/97, *Coca Cola*, (2000) ECR II-1733, para. 82.

¹³⁶ Commission Notice on the definition of the relevant market, OJ C 372 (9.12.1997) p. 3, para. 12.

ATC classification can itself be applied in Article 82 EC cases without further reflection on substitutability.

The ATC system was originally intended to provide a useful method of pharmaceutical product categorisation for statistical, population-based analyses and evaluation of health policy.¹³⁷ The ATC 3, however, does not necessarily reflect the therapeutic use which is one point to consider substitutability. The WHO notes:

"(...) assignment to different ATC groups does not mean difference in therapeutic effectiveness and assignment to the same ATC group does not indicate therapeutic equivalence."¹³⁸

Further, the ATC classification does not reflect on the substitutability of the pharmaceutical product with all aspects that a doctor takes into account when prescribing a product. And, the ATC classification does not reflect on the specific circumstances of an Article 82 EC case. It does not take into account all other criteria set out above to define the market, e.g. the competitive conditions or the structure of supply and demand.

While the ATC classification might be useful for statistics and could be helpful to follow and compare trends in consumption of medicines, and thus for the evaluation of market power of a company, it is not comprehensive enough to reflect on the substitutability, the intended use, the supply structure and the attitudes of the consumers and thus the given nature and importance of a pharmaceutical product.

(iii) *Conclusion*

The analysis of the ATC 3 level might be a useful way to ascertain whether there are major overlaps for the products in question that might lead to concerns of the effect of a merger on the market in future.¹³⁹ The ATC 3 is, therefore, a possible starting point for the classification of a market and the approach taken in the merger decisions might give a first indication on factors that need to be considered.¹⁴⁰

However, each analysis needs to determine whether products of one ATC 3 level might be further subdivided on the basis of a variety of criteria, in particular demand-related criteria¹⁴¹ and specific supply structures. Therefore, market definition in an Article 82 EC case must go beyond the ATC classification to achieve a result that reflects the aim of the market definition, namely to provide the analytical frame for the assessment of dominance and its abuse.

The Commission has in principle already accepted this for market definition in Article 81 EC cases. In its decision *Glaxo Wellcome* it referred to the ATC classification merely as a starting point.¹⁴² However, the Commission did not elaborate on the further assessment since the agreement in question concerned all Glaxo Wellcome products sold in Spain. Therefore, the Commission concluded, it was not necessary to assess the market for individual products. In the *Bayer/Adalat* decision, on the other hand, no reference at all

¹³⁷ See chapter use and misuse at <http://www.whocc.no/atcddd/>.

¹³⁸ See chapter use and misuse at <http://www.whocc.no/atcddd/>.

¹³⁹ See also Commission Notice on the definition of the relevant market, OJ 1997 C 372 p. 3, para. 10.

¹⁴⁰ *Stephanie Pautke, Keith Jones*, Competition Law limitations for the distribution of pharmaceuticals – rough guide to the brave world, ECLR 2005, 24, 28.

¹⁴¹ Commission Decision of 8 May 2000, Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham; Commission Decision of 22 May 2000, Case COMP/M.1878 – Pfizer/Warner-Lambert; Commission Decision of 27 February 2003, Case COMP/M.2922 – Pfizer/Pharmacia.

¹⁴² Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001) p. 1, para. 111.

was made to the ATC classification.¹⁴³ The case was limited to a single product to which the agreements referred, namely Adalat.

(c) *National approaches*

National decisions in different Member States support the view that the Commission approach to define markets in merger cases in the pharmaceutical sector is not the *ultima ratio*. Although ATC is used, there are mainly other factors that are decisive. It also results in the finding that market definitions on the national level in general tend to be narrower.

- **France**

According to the French Competition Council (Conseil de la Concurrence), in general the following criteria are relevant for the assessment of substitutability of two pharmaceuticals in cases that concern the abuse of a dominant position: the effects and counter-effects, the pharmaceutical properties and the opinion of the physician prescribing the pharmaceutical.¹⁴⁴

In a 2004 decision passed in an interim relief proceeding, the Competition Council also considered further factors when defining the market.¹⁴⁵ Aside from the factors specified above, the Council included the distribution structure for pharmaceuticals and the impact of the public service obligation into its deliberations on the market definition.¹⁴⁶ These deliberations led the Council to the conclusion that the distribution of each pharmaceutical protected by a patent can qualify as its own separate market.

- **Germany**

In Germany there are numerous decisions of the Federal Cartel Office (Bundeskartellamt) and review decisions of the courts that concern the pharmaceutical sector.¹⁴⁷ The ATC classification has been mainly used to define the market in merger decisions.¹⁴⁸ In antitrust cases, however, the German Federal Court of Appeal (Bundesgerichtshof) focused as early as 1976 on the regular prescription practise of doctors as far as they are based on scientific reasoning.¹⁴⁹ A main factor considered by the court was that the doctor takes into account the adverse effects, toxicity and tolerance when opting for a specific pharmaceutical.

- **Greece**

The Greek Competition Commission (Epitropi Antagonismou) concluded in a still pending case that each of the pharmaceutical products in question, i.e. Lamictal, Imigran and Serevent, constitute a separate market because pharmaceuticals that are only available on prescription cannot be substituted by the pharmacist and are therefore *ad defintionem* each an individual market.¹⁵⁰

Additionally, the Competition Commission noted that it would have come to the same conclusion if the market was defined on the basis of the individual active substance of

¹⁴³ Commission Decision of 10 January 1995, Case IV/34.279/F3 – Adalat, OJ L 201 (9.8.1996) p. 1, para. 153.

¹⁴⁴ Décision du conseil de la concurrence no. 03-D-35, 24 July 2003 (Sandoz); Décision du conseil de la concurrence no. 01-D-23, 10 Mai 2001 (Abbott).

¹⁴⁵ Décision du conseil de la concurrence no. 04-D-05, 24 February 2004 (Phoenix Pharma).

¹⁴⁶ Décision du conseil de la concurrence no. 04-D-05, 24 February 2004 (Phoenix Pharma) para. 34 et seq.

¹⁴⁷ Bundesgerichtshof, decision of 12.2.1980, WuW/E BGH 1678, 1681 (Valium II), Annual Report of the BKartA 1981/82, p. 58, 1983/84, p. 84, Kammergericht, decision of 19.3.1975, WuW/E OLG 1599, 1603 (Vitamin-B-12).

¹⁴⁸ Kammergericht, Kart. 18/93 – *Fresenius/Schiwa*, decision of 18.10.1995, WuW 1996, 619, 627.

¹⁴⁹ Bundesgerichtshof, decision of 16.12.1976, KVR 2/76, GRUR 1977, 269 (Valium I).

¹⁵⁰ Decision 193/III/2001 of 3 August 2001, Glaxo Wellcome, GRURInt 2002, 534.

each product since there is only one producer for each of them in Greece. Also, a market definition on the basis of therapeutic substitution that would include products with other active substances would result in a product market limited to each of the single products since from the viewpoint of the doctor and taking into account the patient's condition each product is non-substitutable. This market definition was recently confirmed by a decision of the Court of First Instance in Athens.¹⁵¹

- **Italy**

The Italian competition authority (Autorita garante della concorrenza e del mercato) is also focusing on the therapeutic substitutability and the assessment of the doctor, referring to the mode of operation, possible side-effects and the impact on different individuals in different clinical situations.¹⁵² Recently the Milan Court of Appeal in an interim proceeding considered further that once the doctor has made his choice it is irreplaceable. Because of this rigidity of the medical prescription system, the downstream market for the distribution of pharmaceuticals after the doctor has made a choice needs to be defined more narrowly. On this market products are not substitutable unless generics exist.¹⁵³

- **Netherlands**

From the perspective of the Dutch competition authority (Nederlandse Mededingingsautoriteit) the demand substitutability of pharmaceuticals depends on their therapeutic effect according to the assessment of the prescribing doctor. In that context the Dutch competition authority references a market definition according to the ATC 3 level also in antitrust decisions.¹⁵⁴

On the supply side as well, the therapeutic effect is considered to be decisive. Again, the ATC 3 level is a connecting point, as is the classification under the Dutch pharmaceutical refund system.

- **Spain**

In cases analysing behaviours such as i.e. refusal to supplies, dual-pricing systems, etc. under Article 82 EC and its equivalent under national law¹⁵⁵, the Spanish Competition Authority (Tribunal de Defensa de la Competencia, TDC) has generally applied the third level of the ATC classification.¹⁵⁶

In some specific cases, the applied product market definition has led the TDC to conclude the existence of an abuse of a dominant position. For instance, in a case concerning *Glaxo*, following the establishment of its dual price system¹⁵⁷, it stated that:

“the therapeutic areas constitute different markets in which in principle the position of the operators is more appreciable because the substitution or equivalence is being produced between the pharmaceutical products that have the same therapeutic utility and not between those that have different therapeutic purposes”.

¹⁵¹ Decision 1124/2005 of 28 February 2005, Pharmacon - Dimitris Politis SA v. GlaxoSmithKline S.A.

¹⁵² Decision 14388 of 15 June 2005, Merck – active ingredients.

¹⁵³ Decision of 12 July 2005, case 2056/2005, Farmacia Petrone v Pharmacia Italy and Pfizer Italy (not published).

¹⁵⁴ Besluit 1994/76 of 9 July 2002 – Astra Zeneca; Besluit 1915 of 23 August 2001 – Zilveren Kruis Geneesmiddelenformulairum Kennemerland.

¹⁵⁵ Article 6 of the Ley de Defensa de la Competencia (Spanish Competition Act).

¹⁵⁶ TDC Resolution of 22 September 2003 (Expte. R 547/02, Cofares/Organon); TDC Resolution of 5 December 2001 (Expte. R 488/01, Laboratorios Farmacéuticos).

¹⁵⁷ TDC Resolution of 16 October 1998 (Expte. MC 29/98, Glaxo).

On this basis, the TDC stated that Glaxo had a strong position in the market with regard to some of its branded medicines. It also pointed out that those wholesalers that were not able to supply Glaxo's medicines to the pharmacies would be seriously damaged, given that the orders of the pharmacies would be redirected to other wholesalers able to supply all brands.

- **UK**

In the UK there are two recent cases which dealt with the dominant positions of pharmaceutical companies.¹⁵⁸ In both cases the Office of Fair Trading (OFT) and the Competition Appeal Tribunal referred to the ATC classification as a starting point but then turned to the evaluation of other criteria that are based on a more therapeutic use approach.

In the *Napp* case, for instance, the OFT had a closer look at the prescription habits and the operating mechanism of the products (sustained release v. immediate release). It first excluded a group of products from the same ATC 3 level because the clinical uses and clinical needs were different (morphine opposed to non-morphine products). In the next step it differentiated two separate markets on the basis of the operating mechanism: an immediate-release and a slow-release segment.¹⁵⁹

In the *Genzyme* case the Competition Tribunal affirmed the findings of the OFT that it was essentially the effective treatment of the particular disease which was decisive.

"(...) an undertaking's market power will depend on whether the consumers or users of the product have any alternatives available to them. It is thus the market in which substitutes are, or are not, available that is the relevant market for the purpose of addressing the issue of dominance."¹⁶⁰

In this particular case, there were only two products that were considered an effective treatment. Therefore, the market comprised only two products. Other arguments raised by the pharmaceutical producer to argue for a wider market definition, e.g. that the disease belonged to a disease family in which R&D, production and marketing as well as the methods of treatment are basically the same, could not convince the Competition Tribunal to change its findings.

Accordingly, the Competition Tribunal concluded that in a case where for a disease is only one treatment available the market would be limited to this particular product.¹⁶¹

- **US**

In the US the approach to market definition in the pharmaceutical sector seems to differ broadly between decisions of the Federal Trade Commission (FTC) and cases of private litigation. The assessment of the relevant product market in pharmaceutical merger cases is in general limited to medicines in an individual therapeutic category.¹⁶² Practice shows, however, that other criteria also play an essential role. The relevant product market has, for instance, also been defined as narrowly as a

¹⁵⁸ Decision of the Director General of Fair Trading NCA98/2/2001 of 30 March 2001- Napp Pharmaceutical Holdings Limited and Subsidiaries (Napp); Decision of the Competition Appeal Tribunal, Case 1016/1/03 of 11 March 2004 – Genzyme Limited (Genzyme).

¹⁵⁹ Decision of the Director General of Fair Trading NCA98/2/2001 of 30 March 2001- Napp Pharmaceutical Holdings Limited and Subsidiaries (Napp), para. 81.

¹⁶⁰ Decision of the Competition Appeal Tribunal, Case 1016/1/03 of 11 March 2004 – Genzyme Limited (Genzyme), para. 216.

¹⁶¹ Decision of the Competition Appeal Tribunal, Case 1016/1/03 of 11 March 2004 – Genzyme Limited (Genzyme), para. 219.

¹⁶² *David Balto/James Mongoven*, Antitrust Enforcement in Pharmaceutical Industry Mergers, Food and Drug Law Journal, 1999, p. 255.

specific compound or the manner in which that compound interacts with the body and even more narrowly as a once-a-day use of the medicine, where buyers perceive a separate market for different dosage forms.¹⁶³

One author has summarised the different criteria that have been used in the US to define a market in the pharmaceutical sector as the following:

*"(1) whether drugs treat the same disease, condition, or indication; (2) whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they have the same "mechanism of action"); (3) whether drugs have the same specific chemical compounds; (4) whether drugs have the same dosage form such as injectable, liquid, capsule, tablets, or topical; (5) whether drugs have the same frequency of dosage, such as once-a-day or extended release; (6) whether drugs have the same strength of dosage, distinguishing, for example, 30mg and 60mg tablets; (7) whether drugs are branded or generic; (8) whether drugs require a prescription or are sold over-the-counter; and (9) whether drugs are currently marketed or are in development."*¹⁶⁴

Although the US has a different regulatory environment and conclusions from the case law are not necessarily applicable to the European market, the analytical approach still provides an informative basis for any assessment of the market in Article 82 EC cases.

(d) *Commission approach and national approaches revised – Criteria to define therapeutic substitutability*

From the arguments brought forward in these national and Commission decisions one can extract a number of criteria that need to be considered when deciding about therapeutic substitutability.

(i) *Prescription habits*

The majority of national decisions reflected on the prescription habits of the doctors when defining the market for pharmaceuticals. This is because the doctor is the one that makes the decision about the product. It is the doctor who in the first instance chooses. This basically reflects the general approach to look at the consumer preferences when defining the relevant product market.¹⁶⁵ The Commission stated that:

*"The interchangeability of products depends in principle not on their physical, technical or chemical properties but on their functional substitutability as viewed by those supervising their consumption. In the case of medicines available on prescription only, therefore, these would be established medical practitioners."*¹⁶⁶

The diagnosis of the doctor constitutes the starting point for his decision on how to treat the particular illness.¹⁶⁷ When deciding for a medicinal treatment the doctor has to reflect on several aspects, such as the patient's condition or possible contraindications (see below). Prescribing habits might also vary geographically and within the different medicinal sectors.

¹⁶³ Order of the FTC of 14 June 1995, C-3586, Glaxo PLC, 119 FTC 815; Order of the FTC of 5 December 1995, C-3629, Hoechst AG, 120 FTC 1010.

¹⁶⁴ *Howard Morse*, Product market definition in the pharmaceutical industry, 71 Antitrust L.J. 2003, p. 33 with further references to case law.

¹⁶⁵ See e.g. Commission Decision of 22 January 1997, Case No IV/M.794 - Coca-Cola/Amalgamated Beverages GB, OJ L 218 (9.8.1997) p. 15, para. 30 et seq.

¹⁶⁶ Case IV/M.737 – Ciba-Geigy/Sandoz; Commission Decision of 4 February 1998, para.21.

¹⁶⁷ Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome OJ L 302 (17.11.2001) p. 1, para. 111.

The prescribing behaviour has been used by the Commissions in *Pfizer/Pharmacia*: although belonging to the same ATC 3 level the antibiotics in question were in general prescribed for different pathologies and therefore held not substitutable.¹⁶⁸ In *Glaxo Wellcome/Smithkline Beecham* the Commission identified a product (Imigran) to be: "*the gold standard in symptomatic treatment of acute migraine*"¹⁶⁹ in view of the doctors.

Moreover in *Bayer/Adalat* the Commission noted that:

*"in the medicinal products sector, doctors and patients are often very attached to a particular brand, particularly in the case of chronic diseases."*¹⁷⁰

In *Glaxo Wellcome/Smithkline Beecham* it was the parties that argued:

*"that where a drug has a well established efficacy and safety profile, a physician is likely to choose it and will consistently prescribe it for the majority of patients unless there are strong reasons not to."*¹⁷¹

And a UK study found out that:

*"doctors choose the drugs they prescribe primarily on the basis of their clinical efficacy, safety, tolerability and convenience to the patient, in that order."*¹⁷²

Therefore, in its decision the doctor might reflect on the following individual issues:

- **First and second intention:**

The decision might be influenced by rating two intentions of treatment. In *Pfizer/Pharmacia* the Commission based its assumption that two products do not compete with each other on the fact that one of the products would be used only as second line treatment while the other product would be contra-indicated and/or would not produce results. This was mainly due to the fact that a treatment by a pill (Viagra) would always be the preferably course compared to an injection (injection to the penis).¹⁷³ The same principle was applied in *Astra/Zeneca* with regard to plain and combined medicines (see further below).

- **Contraindications:**

Further, the decision of the doctor will be influenced by the contraindications of each pharmaceutical. De facto contraindications of one product can make another product the only alternative for treatment.¹⁷⁴

- **Patient's condition:**

The patient's condition is an important factor to consider in the choice of medication. This does not only include potential adverse effects of a product but also the interaction of various medicines or the consideration of other diseases and/or the current stage of the patient's illness.

¹⁶⁸ Commission Decision of 27 February 2003, Case COMP/M.2922 – Pfizer/Pharmacia, para. 56.

¹⁶⁹ Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham; Commission Decision of 22 May 2000, para. 196.

¹⁷⁰ Commission Decision of 10 January 1995, Case IV/34.279/F3 – Bayer/Adalat, OJ L 201 (9.8.1996) p. 1, para. 28.

¹⁷¹ Commission Decision of 8 May 2000, Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham.

¹⁷² Department of Health, PPRS: the study into the extent of competition of supply of branded medicines to the NHS, 2002, p. 6.

¹⁷³ Commission Decision of 27 February 2003 Case COMP/M.2922 – Pfizer/Pharmacia, para. 42.

¹⁷⁴ Commission Decision of 26 February 1999, Case COMP/M.1403 – Astra/Zeneca; Commission Decision of 27 February 2003 Case COMP/M.2922 – Pfizer/Pharmacia.

"Substitutability among medicines may not only depend on the intrinsic characteristics of the drug themselves, but also their intended use, and particularly each individual patient's condition".¹⁷⁵

If, furthermore, patients are adjusted to one particular pharmaceutical they will switch to another medication in the course of therapy only in exceptional cases, for the Commission has found that

"a switch will include risks for serious side effects, as well as additional costs."¹⁷⁶

For the question of substitutability of specific pharmaceuticals, it might thus very well be relevant whether substitutability, even if theoretically given, is not virtually excluded or reduced to a minimum due to the condition of the patient or specific groups of patients.

(ii) *Product characteristics*

On the basis of particular characteristics of a product substitutability can be further limited. With respect to pharmaceuticals in particular the working mode or the composition of the active ingredients can make a medicine non interchangeable for a certain medical indication. The characteristics of a medicine can also require that a product is only used in a hospital.

• **Different mode of action:**

Although the same active ingredient might be effective, it is the mode of action that can make a particular drug more suitable for treatment and can be of *"decisive importance"*¹⁷⁷ for the question of substitutability. The requirements of the indication will decide if either a quick or moderate or a direct or indirect effect or a high or small doses is necessary. This has already been shown in a number of cases.

In *Astra/Zeneca* the Commission differentiated markets between general and local anaesthetics because of the *fundamentally* different ways they operate. Additionally, clinical factors have been held as determining factors in cases where theoretically a substitution might be possible.¹⁷⁸ In the same decision the Commission pointed out that there are clear differences between short-acting relieving agents for asthma and long-term management anti-asthma products. Similar in the British *Napp* case the immediate-release segment for morphine was held to be a separate market opposed to the sustained-released version of morphine.¹⁷⁹

• **Plain or combined medicines:**

Also, the composition of active ingredients in a drug affects its substitutability. A combined product has more than one active ingredient and aims to treat two or more symptoms. It can only be applied in cases where all these symptoms exist.

Therefore, in *Astra/Zeneca* a plain beta-blocker was held to be the first line treatment while combined products were normally seen as second line treatment where a plain

¹⁷⁵ Commission Decision of 29 April 1993, Case IV/M.323 – Procordia/Erbamont.

¹⁷⁶ Commission Decision of 26 February 1999, Case COMP/M.1403 – Astra/Zeneca, para. 18.

¹⁷⁷ Commission Decision of 17 May 1999, Case COMP/M.1397 – Sanofi/Synthelabo; Commission Decision of 26 February 1999, Case COMP/M.1403 – Astra/Zeneca; Commission Decision of 27 February 2003, Case COMP/M.2922 – Pfizer/Pharmacia.

¹⁷⁸ Commission Decision of 26 February 1999, Case COMP/M.1403 – Astra/Zeneca, para. 36.

¹⁷⁹ Decision of the Director General of Fair Trading NCA98/2/2001 of 30 March 2001 – Napp Pharmaceutical Holdings Limited and Subsidiaries (Napp).

product had been proved to be insufficient.¹⁸⁰ The Commission also established in this case a clear clinical preference for combined products in some countries.

Further, the possibility to switch from a plain drug to a combined product and vice versa might not always be possible. Where a change from one kind of product to another is excluded from a medical point of view, products cannot belong to the same category.

- **Hospital or community use:**

A distinction has to be made between place and mode of usage, particularly between hospital use and community use.¹⁸¹ There are products that are typically used in hospitals because they require certain equipment or specific care and are, therefore, not substitutable to products that can be used at home.

When a product is used on both segments one has to take also into account that the hospital segment is a strategic gateway.¹⁸² Hospitals do not only establish the reputation of a pharmaceutical which influences the prescription behaviour of private practitioners, but they have in a number of cases decisive influence on the future treatment of a disease when deciding for a medicine on long term treatment.

- **First and second generation medicines:**

The Commission has considered the exchangeability of first and second generation drugs.¹⁸³ Although they have the same indication, first and second generation drugs can have differences in frequency of administration and bioavailability that makes them more attractive for the one or other method of treatment.

(iii) *Conclusion*

The evaluation shows that therapeutic substitutability of a pharmaceutical product is subject to numerous criteria and depends on a variety of circumstances.

The ATC classification only sets a rough framework for a more detailed evaluation. Depending on the pharmaceutical, various interactions between the various criteria further restrict the market definition of ATC 3 level.

Since it is the doctor who makes the decision when it comes to the prescription of pharmaceuticals, the doctor's prescribing habits are of particular significance for the assessment of substitutability. Ideally, the doctor is familiar with all available therapy alternatives, and his prescribing habits are not influenced by other factors such as advertising, or marketing and sponsoring campaigns of companies of the pharmaceutical industry. However, in practice this is certainly not the case.

Due to the interaction between the various criteria set out above, the choice might in the end be reduced to merely a few or even only one product.

1.4 *The structure of supply and demand – One-product-one market*

The analysis of the existing decisions shows that the main focus when defining a market was applied to whether the product could be substituted or not. It has hence been argued

¹⁸⁰ Commission Decision of 26 February 1999, Case COMP/M.1403 – Astra/Zeneca, para. 22.

¹⁸¹ Commission Decision of 8 May 2000, Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham.

¹⁸² *Stephen Koen, Sarah Turnbull*, Pricing and the dominant firm: implications of the competition commission appeal tribunal's judgement in the Napp case, ECLR 2003, p. 77.

¹⁸³ Commission Decision of 8 May 2000, Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham, para. 22 et seq; see also the Order of the FTC of 26 January 2001, C-3990, Glaxo Wellcome plc & SmithKline Beecham.

that the mere fact that the doctor chooses the pharmaceutical is decisive for the market definition.¹⁸⁴

However, this is only one element within a larger picture. As indicated above, when defining a market the substitutability of the product is just one criterion besides others which need to be investigated in each single case.

Consideration must be taken as well of the structure of supply and demand and the competitive conditions in the market. In particular these factors are relevant when defining the market for analysing anti-competitive behaviour in a vertical relationship. Moreover, in the case of pharmaceuticals one cannot ignore the peculiarities that influence the behaviour of all parties involved in commercial transactions. The structure of supply and demand in the pharmaceutical sector is unique and needs therefore to be recognised in the market definition.

Thus, the relevant factors will again be summarised hereinafter, followed by an evaluation of their impact on the market definition.

(a) *Public service obligation*

The public service obligation of wholesalers and manufacturers essentially determines the functioning of the market for pharmaceuticals. Its impact is not reduced to the conduct of those subject to the obligation but also extends to that of the other parties being part of the distribution chain for pharmaceuticals.

Besides the criteria specified above which restrict the doctor's choice, one has to take into account the fact that due to the public service obligation of wholesalers and manufacturers, doctors writing prescriptions will - as a rule - assume that a pharmaceutical is available at any time.

In contrast to other markets, where consumers would opt for another, equivalent product in case the product of choice were not available (or its price had undergone an above average increase), physicians are not faced with the unavailability of a product. The decision for a particular product is, therefore, not influenced by any of the otherwise usual criteria.

(b) *Supply chain*

The reciprocity between public service obligation and asymmetric behaviour of the individual parties of the supply chain, which is complex in itself already (see chapter II, section 3), is further complicated by the fact that neither pharmacists nor wholesalers can replace any orders for specific pharmaceuticals they have accepted by delivery of alternative products.

As explained above, and demonstrated by means of several national examples in **Annex III**, only doctors have a choice between therapeutically substitutable products. Neither pharmacists nor wholesalers have the possibility of therapeutic substitution. Even in cases where the doctor only prescribes an active ingredient, a certain product is predicted as in most cases it is the active ingredient itself or its producing process that is under patent protection.

In some countries pharmacists have the possibility and/or obligation to replace a pharmaceutical prescribed by a doctor by a generic or a product available as parallel import. Since this study proceeds from the assumption that there is no generic on the market yet, the only possibility available to the pharmacist is to offer the parallel imported product as the only cheaper alternative, if available.

¹⁸⁴

EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical wholesalers?, 2004, p. 5.

(c) *Consequences for the market definition*

While in standard cases of vertical distribution chains the market definition rightly points at the consumer preferences to assess the substitutability one cannot equally apply this principle to the pharmaceutical distribution chain.

In standard cases substitutability on the level of the end consumer can be equally applied to all levels in the distribution chain – e.g. retailers, wholesalers - to define the market. If the end consumer demands product A from a retailer, who does not have the product in stock, the consumer will usually switch to a substitutable product B or, alternatively, try to receive product A from another retailer. The first retailer will of course try to convince the end consumer to buy product B.

The situation is similar on the next level. If the retailer demands product A from a wholesaler, who does not have the product in stock, the retailer might still buy a substitutable product B. The wholesaler might even use incentives such as discounts to convince the retailer to buy product B, since consumers consider it as substitutable to product A. Accordingly, the substitutability that exists for end consumers also exists continually on all levels of distribution.

However, in the pharmaceutical sector the peculiarities of the distribution chain prevent such a continuous substitutability from the level of the doctor the level of the pharmacies or pharmaceutical wholesalers.

The prescription of a particular product or active ingredient by the doctor obliges the pharmacist to dispense exactly that product or the active ingredient and nothing else. The pharmacist cannot try to convince the patient to buy product B instead of product A if the later is not available. Last but not least because of the public service obligation the doctor assumes that the product he prescribes is available at any time and the pharmacist will be able to supply.

Similar assumptions have to apply for the higher level in the supply chain. In the case where the pharmacist orders product A from the wholesaler, the wholesaler cannot alternatively deliver product B since product B cannot be dispensed to the patient by the pharmacist.

This shows that the question of therapeutic substitutability is a useful starting point for the market definition in cases involving pharmaceuticals. However, because of the particularities that apply to supply and demand for pharmaceuticals the therapeutic substitutability existing on the level of the doctor does not prevail on the other levels of the supply chain.¹⁸⁵ For the wholesaler there is no substitutability for the products he has to supply. He is therefore depending on the supply from the producer of the particular pharmaceutical product.

The rigidity of the medical prescription and distribution system cannot be neglected in the assessment of abusive behaviour under Article 82 EC and leads to the final conclusion that the market on which the wholesalers are active needs to be considered as a market for each individual pharmaceutical product.¹⁸⁶

¹⁸⁵ See e.g. Commission Decision of 10 January 1995, Case IV/34.279/F3 – Bayer/Adalat, OJ L 201 (9.8.1996) p. 1, para. 28, where the Commission noted in this respect: *"It must therefore be borne in mind that, where [a medicinal product] is expressly prescribed by the doctor, it is often difficult to substitute another, competing product, for example a generic, for it, both for psychological reasons (reluctance on the part of the patient to accept another product) and for statutory reasons (statutory rule in some countries prohibiting pharmacists from substituting a product having equivalent therapeutic properties for the product specifically prescribed by the doctor).*

¹⁸⁶ See e.g. Milan court of appeal, decision of 12 July 2005, case 2056/2005, Farmacia Petrone v Pharmacia Italy and Pfizer Italy (not published).

(d) *Conclusion*

The peculiarities of the pharmaceutical market – prescription of a product or active ingredient by the doctor and no possibility for the wholesaler or the pharmacist to substitute – lead to the consequence that therapeutic substitutability in the view of the doctor cannot be applied for the definition of the relevant market between pharmaceutical producers and wholesalers in cases of Article 82 EC. One has to consider that a refusal to supply a wholesaler with a certain pharmaceutical product leaves the wholesaler no possibility to sell an alternative product. Consequently the relevant market can only be defined as the prescribed individual pharmaceutical product. The one-product-one-market approach is applicable.

It has been argued that such an approach would lead to the consequence that also small pharmaceutical undertakings would be deemed to have market power.¹⁸⁷ However, this position does not consider that the significant issue under Article 82 EC is not the size of the undertaking but only the question of market power.¹⁸⁸

Furthermore, there are numerous examples in case law which show that also small firms can be dominant or markets can be defined narrowly. In cases concerning spare parts, for example, companies that have only a small market share in the overall market were held dominant in the market for spare parts of its machines.¹⁸⁹ A single port or airport was held to be a separate market for the organisation of service activities.¹⁹⁰

With regard to pharmaceuticals the UK Competition Tribunal commented on the above cited argument like this:

*"Nor,(...), is it conceptually absurd that, in a sector such as pharmaceuticals, or even in a sub-sector such as orphan drugs, there may be a large number of small relevant markets in which there is a dominant supplier. Consumers in small markets are, in our view, just as entitled to the protection of the Chapter II prohibition as are consumers in larger markets. That applies particularly to persons suffering from a disease for which there is only one treatment, irrespective of whether the disease itself is rare or not."*¹⁹¹

Furthermore, as elaborated above, the market definition in an Article 82 EC case does not necessarily apply in a merger case and the other way around. Accordingly, concerns that a one-product-one-market approach in Article 82 EC cases would lead to problems in merger control cases cannot be upheld.

1.5 *Geographic market*

In its merger decisions the Commission repeatedly stated that the geographic market should be considered as national. In the absence of harmonisation the different national authorisation and national price regulation systems would define the individual characters of national markets.¹⁹² Further, the Commission stated that

¹⁸⁷ *EFPIA*, Article 82 EC: Can it be applied to control sales by pharmaceutical wholesalers?, 2004, p. 25.

¹⁸⁸ *Richard Wish*, *Competition Law*, 2003, p. 192.

¹⁸⁹ Commission Decision of 8 December 1977, Case IV/29.132 – *Hugin/Liptons*- OJ L 22 (27.1.1978) p. 23 (although the decision was annulled on appeal the ECJ upheld the finding on dominance, Case 22/78, *Hugin*, (1979) ECR 1869).

¹⁹⁰ Case C-179/90, *Porto di Genova*, (1991) ECR I – 5889; Commission Decision of 14 January 1998, Case IV/34.801 – FAG -Flughafen Frankfurt/Main AG – OJ 1998 L 72/30.

¹⁹¹ Decision of the Competition Appeal Tribunal, Case 1016/1/03 of 11 March 2004 – *Genzyme Limited* (*Genzyme*), para. 219.

¹⁹² Commission Decision of 3 April 1995, Case IV/495 – *Behringwerke AG/Armour Pharmaceutical Co.*; Commission Decision of 13 September 1996, Case IV/M.781 – *Schering/Gehe-Jenapharm*.

*"[i]n view of these regulatory constraints, and given different medicine distribution systems, national brands, and different consumer preferences, pharmaceutical markets remain essentially national."*¹⁹³

Although the parties pointed to an increasing harmonisation of the European pharmaceutical market including harmonisation of technical and registration provisions the Commission continued to define the markets on a national basis, arguing that the sale of medicines is still mainly influenced by the regulatory schemes and far-reaching differences in terms of brand and pack size strategies and in distribution systems.¹⁹⁴

In Article 81 EC decisions the Commission has also argued that, despite the harmonisation of the technical legislation regarding pharmaceuticals, markets remain national because the sale of medicines is influenced by the administrative or purchasing policies adopted by the individual national health services,¹⁹⁵ the regulatory schemes and differences in terms of brand and pack size strategies and in distribution systems as well as different prescribing habits of doctors.¹⁹⁶

The same should apply for Article 82 EC cases, especially if one has to assess a certain behaviour of the pharmaceutical industry towards wholesalers in a specific country because both the relationship and the wholesalers' behaviour depend on the national regulatory scheme in that country.

1.6 Conclusion

The relevant market where the pharmaceutical manufacturer and the wholesaler are present, and which forms the basis for an assessment according to Article 82 EC, is the distribution of one certain pharmaceutical product. Despite the fact that a certain degree of substitutability might exist between pharmaceutical products, in the sense of therapeutic substitutability on the doctor's level the structure of supply and demand in the pharmaceutical industry leads to the one product-one market approach.

Geographically the market is determined by the national regulatory schemes. In accordance with the existing case law the relevant market is thus to be defined on national bases.

Even if one chooses a market definition where the therapeutic substitutability on the doctor's level is considered to be decisive it will lead in most cases to only two or three different pharmaceuticals that fulfil the criteria set out above or even only one product, as for example Lamictal in the *Syfait* case,¹⁹⁷ that could define the market.

¹⁹³ Commission Decision of 20 June 1994, Case IV/M.457 – La Roche/ Syntex.

¹⁹⁴ Commission Decision of 16 July 1996, Case IV/M.737 – Ciba-Geigy/Sandoz; Commission Decision of 4 February 1998, Case IV/M.950 – Hoffmann La Roche/Boehringer Mannheim; Commission Decision of 9 August 1999, Case IV/M.1378 – Hoechst/Rhone-Poulenc; Commission Decision of 8 May 2000, Case COMP/M.1846 – Glaxo Wellcome/Smithkline Beecham; Commission Decision of 27 February 2003, Case COMP/M.2922 – Pfizer/Pharmacia.

¹⁹⁵ Commission Decision of 10 January 1995, Case IV/34.279/F3 – Adalat, OJ L 201 (9.8.1996) p. 1, para. 150-152.

¹⁹⁶ Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001) p. 1, para. 114.

¹⁹⁷ Decision 193/III/2001 of 3 August 2001, Glaxo Wellcome, GRURInt 2002, 534.

2. Dominance

2.1 Introduction

The next step in any analysis of Article 82 EC is to prove the market dominance of an enterprise, for only undertakings having a dominant position on the market are subject to the special obligations reflected in Article 82 EC. A firm in a dominant position

*"has a special responsibility not to allow its conduct to impair undistorted competition on the common market."*¹⁹⁸

The test for establishing dominance has been set out by the ECJ as:

*"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 its consumers".*¹⁹⁹

Economically, dominance refers to the ability of an undertaking to raise prices above a competitive level for a substantial volume of sales and over a substantial period of time, thereby enjoying increased profits.²⁰⁰ As shown already in the context of the hypothetical price increase test, criteria that are oriented solely towards price regulation are inapplicable, or applicable only to a certain extent, in the pharmaceutical sector. Therefore, the analysis of dominance in the pharmaceutical sector has to be based mainly on a number of other factors, which taken separately, are not necessarily determinative.²⁰¹ In general, these factors include:

- high, stable market shares especially relative to competitors;
- access to raw materials and capital;
- the technical knowledge and expertise of the undertaking and of its competitors;
- the exclusionary effect of any sales or distribution networks;
- barriers to entry, such as the cost of setting up manufacture;
- the overall strength, i.e. especially financial power;
- the existence of any abusive behaviour.

The assessment of dominance of an undertaking in the pharmaceutical sector must in addition take into consideration the specific circumstances on the market when applying the general principles.

2.2 The market share as most important factor and indication of dominance

A high market share has been held as the principal factor of dominance. The market share of the alleged dominant company gives at least a first indication of its market power – and sometimes more than just an indication. The higher a market share the more market power the alleged dominant company has.

The ECJ in the same way as the Commission assumes that a monopoly regularly leads to dominant position.²⁰² The same applies to a quasi-monopoly with a market share of more than 90%. The ECJ and the Commission regularly assume a dominant position only with reference to the lessening of or a weakening competition.

In this respect the ECJ and the Commission regularly state that

¹⁹⁸ Case 322/81 *Michelin NV v Commission*, (1983) ECR 3461, para.57.

¹⁹⁹ Case 322/81 *Michelin NV v Commission*, (1983) ECR 3461, para.30.

²⁰⁰ *Richard Wish*, Competition Law, 2003, p. 179.

²⁰¹ Case 27/76 *United Brands v Commission* (1978) ECR 207, para.66.

²⁰² *Helmuth Schröter* in Schröter/Jacob/Mederer (Ed.), *Kommentar zum Europäischen Wettbewerbsrecht*, 2005, Article 82, para. 126.

“the existence of very large market shares is highly important and very large shares must be considered in themselves, save in exceptional circumstances, as evidence of a dominant position.”²⁰³

“Very large market shares” are those of more than 70 %.²⁰⁴ Even if the ECJ's and the Commission's practice tend to secure this rule by presenting further arguments, these are normally not necessary.²⁰⁵ Accordingly, in these cases a company is deemed to be dominant.

Market shares between 45% and 70% regularly suggest a dominant position. However, in these cases further factors have to be considered, e.g. the structure of the relevant market, the market share of the next competitor and the distance between them.

Even with a market share between 25% and 45% an undertaking can be in a position to prevent effective competition and therefore be held dominant. However, in such a case the specific factors mentioned above have to be examined in detail.

The application of these principles to the given situation in refusal to supply cases comes to the following conclusions.

(a) *One-product-one market approach results in dominance*

The conclusions on the market definition in the pharmaceutical sector with regard to a limitation or refusal to supply show that the peculiarities of demand, supply and distribution of this sector lead to the application of a one-product-one market approach. Consequently, each manufacturer of a certain pharmaceutical is a monopolist with regard to this product.

In accordance with the above mentioned jurisprudence of the ECJ and with the practice of the Commission this monopoly situation establishes a dominant position in the sense of Article 82 EC. Therefore, the dominance of a pharmaceutical undertaking on a one-product-market should be beyond doubt.

(b) *The therapeutic substitutability approach results in dominance*

Even if the market definition does not take into account the peculiarities of demand and supply and, therefore, only considers the therapeutic substitutability, one will still come to the conclusion of dominance.

In the case of a market definition based on therapeutic substitutability the product market will comprise not only the product of the alleged dominant company but eventually also such products that are therapeutically substitutable.

In the majority of cases it is, however, to be expected that this wider market definition approach will also lead to a relevant product market containing only one product for which there is no existing substitution. This was the case, for example, in *Syfait* with the product Lamictal when the Greek Competition Commission found that despite an existing therapeutic substitute GSK had a 100% market share.²⁰⁶ Similarly the Commission found with regard to the product Imigran that:

²⁰³ Case T-30/89, *Hilti*, (1991) ECR II-1439.

²⁰⁴ Case C-62/86, *AKZO Chemie BV v Commission*, (1991) ECR 3359, para.60; Case T-30/89, *Hilti*, (1991) ECR II-1439, para.92.

²⁰⁵ Joined Cases 40-48, 50, etc./73, *Suiker Unie*, (1975) ECR 1480, para. 90 et seq.; Case 85/76, *Hoffmann-La Roche*, (1979) ECR 461, para.41; Case C-62/86, *AKZO Chemie*, (1991) ECR I-3359, para.60; Case T-24 etc./93, *Compagnie Maritime Belge*, (1996) ECR II-1201, para. 76 et seq.

²⁰⁶ Decision of the Greek Competition Commission 193/III/2001 of 3 August 2001, Glaxo Wellcome, GRURInt 2002, 534.

*"In view of its therapeutic characteristics and its high market shares and price, Imigran would currently appear to be a unique product for acute attacks of migraine, at least as far as a significant proportion of migraine patients are concerned."*²⁰⁷

In cases like this the result for the assessment of dominance is the same as with the one-product-one market approach. The factual monopolist is to be held dominant.

Even if therapeutic substitutability leads to a relevant product market with two or more substitutable pharmaceuticals, it is likely that the undertaking which refuses to supply will be dominant. In such a case of two or more existing competitors where there is no monopolist or quasi-monopolist it will be necessary to examine other relevant factors as mentioned above. Thereby, *"it is necessary first of all to examine [the] structure [of the relevant market] and then the situation on the said market as far as competition is concerned"*.²⁰⁸

In *Syfait* the Greek Competition Commission found that in case the relevant market would be defined on the basis of therapeutic substitutability, Glaxo Greece had market shares with regard to Imigran of 43.6% (calculated on quantities) and 81.1% (calculated on market value at wholesale price); Serevent of 61.0% and 63.4% respectively.²⁰⁹ The Greek Competition Commission came to the conclusion that Glaxo Greece had a dominant position also with the regard to these two products notably because of these high market shares, in addition to several other factors

2.3 *Other factors to be considered in finding dominance*

The assessment of other factors than market shares will underline that the assumption of dominance of pharmaceutical undertakings is not only a result of a narrow market definition. Their dominant positions are regularly based on high market shares, high barriers to market entry, especially resulting from existing patents (see lit.(b)), on their economic and financial strengths (see lit.(c)) and can be shown by their behaviour (see lit.(d)). Finally, the dominant character of pharmaceutical undertakings derives from their position as obligatory trading partners for the wholesalers (see section 2.4).

However, in examining the question of market dominance it is necessary to consider one argument used by the pharmaceutical manufacturers, according to which – despite their high market shares which regularly point to dominance – they cannot operate independently from their competitors and customers due to the market mechanisms, and in particular price regulations (see lit.(a)). It is argued that the buying power of the national regulatory authorities could prevent dominance of a single pharmaceutical undertaking because it prevents this company from exercising any kind of pricing power.²¹⁰

(a) *Buyer power in the pharmaceutical sector*

The presence of powerful purchasers with the strength to stand up to a supplier with a large market share can influence the assessment of dominance in a particular market.²¹¹ However, the existence of buyer power as such does not necessarily exclude the application of Article 82 EC.²¹² Rather, also buying power has to be reflected in the

²⁰⁷ Case IV/M.555 – Glaxo/Wellcome; Commission Decision of 16 July 1996, para. 14.

²⁰⁸ Case 27/76 *United Brands v Commission* (1978) ECR 207, para. 67.

²⁰⁹ Decision of the Greek Competition Commission 193/III/2001 of 3 August 2001, Glaxo Wellcome, GRURInt 2002, 534; as mentioned above, concerning the third pharmaceutical Lamictal even the therapeutic substitutability approach led to a market share of 100 %.

²¹⁰ EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004, p. 35-47.

²¹¹ *Bellamy & Child*, European Community Law of Competition, 2001, para. 9-058.

²¹² *Dermot Glynn*, Article 82 and price discrimination in patented pharmaceuticals: the economics, ECLR 2005, 135, 137.

economic circumstances of the market and assessed as to which extent it influences the independence of the pharmaceutical undertakings.

The pharmaceutical industry argues that individual manufacturers cannot be dominant because they are faced with strong buying power. In cases concerning limitation or refusal to supply, however, this is not convincing for at least two reasons. First, dominance is not only based on the competitive parameter price (see (i)). Secondly, the buyer power argument cannot apply in relation to wholesalers. It is the wholesalers that are directly affected, and normal wholesalers do not have any buyer power (see (ii)).

(i) *The relevance of the pricing power argument*

The industry is correct in stating that the assessment of dominance – in merger cases – has to consider a certain degree of buying power by the government or health insurance fund, etc. as they influence “the price”. However, as mentioned above (see chapter II, section 5.2) regulated sales prices and reimbursement levels in general reflect the outcome of negotiations between the pharmaceutical company and the payer, normally a government or health insurance fund. As such, the most plausible assumption is that a monopsonist is facing a monopolist.²¹³ In this situation one has to analyse on a case by case basis the bargaining power of both sides.

In particular the final reimbursement price will reflect the political and economic power of the bargaining skills of both the pharmaceutical undertakings and the government or health insurance fund.²¹⁴ However, with respect to the price negotiations, the pharmaceutical industry has considerable leeway to influence the negotiations and put pressure on governments.

One reason for this is that it is difficult to reconstruct how pharmaceutical undertakings calculate their prices when introducing a product on each national market. So far the pharmaceutical industry has managed to avoid any disclosure of the different criteria used for fixing prices.

Furthermore, a lack of effective substitute products makes it difficult for buyer power to have a real effect.²¹⁵

Moreover pharmaceutical enterprises can delay the introduction of new products so as to negotiate a higher price especially with countries that refer to the prices applicable in other Members States when fixing their own prices. The delay of distribution also qualifies as a form of pressure exerted on governments, which due to their social obligations towards the population are obliged to warrant effective medical care.

This last fact particularly shows that the pharmaceutical industry has influence not only on price-setting but also on other competition parameters which are equally relevant to determine market behaviour and structure.

Consequently, it has to be considered that the pharmaceutical undertakings are free in determining their sales conditions. As mentioned above (see chapter II, section 5.2 lit.(b)), it is regularly also in the discretion of pharmaceutical undertakings to grant rebates, bonuses and discounts to wholesalers (within the legal rules and regulations). Furthermore, pharmaceutical undertakings can directly influence the volumes of the pharmaceuticals delivered.

²¹³ *Dermot Glynn*, Article 82 and price discrimination in patented pharmaceuticals: the economics, ECLR 2005, 135, 137.

²¹⁴ *Alistair McGuire, Michael Drummond, Frans Rutton*, Reimbursement of pharmaceuticals in the European Union, in *Elias Mossialos, Monique Mrazek, Tom Walley (Ed.)*, Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality, 2004, p. 132.

²¹⁵ E.g. Decision of the Competition Appeal Tribunal, Case 1016/1/03, 11 March 2004 – Genzyme Limited, para. 241 et seq.

Therefore, while the pharmaceutical industry might not be free to set sales prices in accordance with changes in the market conditions manufacturers still have the freedom to

- renegotiate prices;
- grant rebates, bonuses and discounts;
- decide whether to place the product on the market or not;
- restrict deliveries especially to avoid competition on neighbouring markets.

It is not by coincidence that the pharmaceutical industry, despite price regulation, manages to steadily increase its turnover.

(ii) *No buyer power of the wholesalers as contracting parties*

In Article 82 EC cases the buyer power argument can only be considered if the undertaking being affected by the alleged abusive behaviour possesses buyer power itself.

There is no relevant EU case law which confirms the applicability of the buyer power argument in Article 82 EC cases on pharmaceuticals.²¹⁶

Just as in the case of market definition the assessment of dominance in merger cases is based on a prospective view of the relevant market. In Article 82 EC cases, however, dominance at the time and in light of the practice under consideration is of relevance.²¹⁷

This means that in limitation or refusal to supply cases the relationship between the pharmaceutical manufacturer and its direct customer, the wholesaler, is central to assessing dominance.²¹⁸ Only the direct recipient of the constraint, i.e. the wholesaler, needs to be considered when evaluating market power. Thus, the buyer power argument could only apply if the wholesalers had buyer power, which is generally not the case.

Accordingly, the main argument of the pharmaceutical industry neglecting the existence of dominance on the pharmaceutical market has to be rejected. A pharmaceutical producer can act independently vis-à-vis the wholesalers to an appreciable extent and is therefore dominant on the product market.

(b) *Barriers to entry*

Another important factor in assessing dominance is the potential competition which the alleged dominant firm faces. Such competition depends primarily on the existence or non-existence of barriers to entry on the market.

Entry barriers are conditions, which make a market less attractive to a potential market entrant.²¹⁹ In the pharmaceutical sector there is an accumulation of different barriers that protect incumbent pharmaceutical undertakings from new competitors.

Primarily, these are the intellectual property rights, in particular the patent protection and the additional protection provided by the SPC (see chapter II, section 4.2). Although the mere ownership of one or more intellectual property rights does not by itself create a

²¹⁶ The *AstraZeneca* decision by the Commission of 15.6.2005 is the first Article 82 EC case in the pharmaceutical sector which found a dominant position. The decision is not published yet, however, it seems that the decision obviously did not explicitly refer to the buyer power argument.

²¹⁷ Also: EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004, p. 37.

²¹⁸ However, this can be different with regard to the hospital sector where hospitals and clinics as direct customers of the pharmaceutical undertakings have in principle the possibility to negotiate discounts and special conditions directly.

²¹⁹ *Bellamy and Child*, European Community Law of Competition, 2001, para. 9-048.

dominant position²²⁰ one cannot ignore that particularly patent rights exclude other parties from the development of competing identical pharmaceuticals.

Further, high costs for research and development and the time frame for the development of new pharmaceuticals are decisive for the market entry of competitors. As the pharmaceutical industry itself points out: the sunk costs are relatively high.²²¹ The length of administrative procedures and the need of a market authorisation for each product add further to the hurdles of market entry.

Accordingly one can conclude that the barriers to entry are quite high in the pharmaceutical sector.

The industry also wants to consider the “availability of effective substitute products, competing pipeline products and generics”²²² when assessing a possible dominant position. Of course the existence of substitute products and the market position of the respective pharmaceutical producers have to be considered – but as actual competitive products. However, this is not related to barriers to entry and potential competition.

On the other hand, in Article 82 EC cases potential competition by pipeline products which are still being researched and developed is normally of no relevance. Pipeline products are only to be considered in merger cases where the assessment of dominance is based on a prospective view of the market.²²³ The same applies to generics, which can only enter the market after the patent of the original product has expired.

(c) *Economic strength and financial power of the pharmaceutical undertakings*

The ECJ has acknowledged in several cases that a company's economic strength and financial power can influence its market position and therefore be relevant in assessing dominance.²²⁴ The same applies to the technological resources of a company.²²⁵

The pharmaceutical undertakings are mostly multinationals with enormous financial power which gives them the opportunity inter alia to invest a high share (about 15-20%) of their turnover in R&D. Furthermore, their worldwide ubiquity allows them for example to restrict supplies into one country knowing that they are able to sell the products in other countries.

This economic strength of most pharmaceutical undertakings increases their ability to behave independently from their competitors and customers and therefore to hinder effective competition.

(d) *Conduct of the allegedly dominant firm*

The ability to behave independently from its competitors and customers can also be inferred from the conduct of the allegedly dominant firm.²²⁶ Although this approach has

²²⁰ Joined Cases C-241/91P and 242/91P, *RTE and ITP v Commission*, (1995) ECR I-743, para. 46.
²²¹ EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004, p. 16.
²²² EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004, p. 39 seq.
²²³ For example Case IV/M.1397 - *Sanofi/Synthelabo*, para. 67.
²²⁴ Case 322/81 *Michelin NV v Commission*, ECR (1983) 3461, para. 55; Commission Decision of 7 October 1981, Case IV.29.491 – *Bandengroothandel Frieschebrug BV/NV Nederlandsche Banden-Industrie Michelin*, (1981) OJ L 353, p. 33, para. 14; Commission Decision of 5 December 1988, Case IV/31.900 – *BPB Industries plc*, (1989) O.J. L 10, p. 50, para. 115.
²²⁵ Commission Decision of 5 December 1988, Case IV/31.900 – *BPB Industries plc*, (1989) O.J. L 10, p. 50, para. 115.
²²⁶ *Faull & Nikpay*, *The EC Law of Competition*, 1999, para. 3.82.

been criticised as circular it has been accepted by the ECJ and is repeatedly applied by the Commission.²²⁷

As for the conduct of pharmaceutical manufacturers discussed in this context, it may be stated in simple terms that manufacturers make use of their market presence in one country (the exporting country) to protect their market presence in another country (the importing country) from competition by parallel distribution.

Pharmaceutical manufacturers' ability to unilaterally influence the circulation of goods by reducing their output on one market to exclude potential competition on neighbouring markets supports the result that they enjoy a "position of economic strength"²²⁸ which allows them to act independently from their competitors and customers.

Finally, by reducing supplies to wholesalers a manufacturer does not run the risk of seeing its products being substituted by competitors' products. As illustrated by the description of the distribution structures, it is not possible for wholesalers to substitute the products.

2.4 *Pharmaceutical undertakings as obligatory trading partners for wholesalers*

Furthermore, one cannot ignore the fact that the pharmaceutical wholesalers depend on the pharmaceutical producers for supplies. From the viewpoint of the wholesalers, pharmaceutical undertakings are "obligatory trading partners".

The concept of "obligatory trading partners" or "partenaire obligatoire" is based on the economic dependence of customers on business partners.²²⁹ It has been recognised by the Commission in reaching its finding of dominance:²³⁰

"The need for traders to include in their range a product which is subject to heavy demand (...) necessarily establishes a relationship of dependence which makes the supplier in question an unavoidable partner."²³¹

The ability of a company to behave independently from its customers reflects the economic dependence of the latter. Customers face a lack of alternative sources of supply due to insufficient competition on the supplier level.²³²

Therefore, in cases where a single or only a few manufacturers supply the market, the customers' dependence results in a dominant position of either the sole or leading supplier.²³³

The distribution chain for pharmaceuticals shows the specific characteristics that make pharmaceutical undertakings an "obligatory trading partner" for wholesalers.

²²⁷ Case 27/76, *United Brands v. Commission*, (1978) ECR 207, para. 8; for further examples see *Richard Wish*, *Competition Law*, 2003, p. 187.

²²⁸ Case 322/81, *Michelin NV v Commission*, (1983) ECR 3461, para. 30.

²²⁹ For the concept of "obligatory trading partner" see also *Richard Wish*, *Competition Law*, 2003, p. 186.

²³⁰ T-229/94, *Deutsche Bahn*, ECR (1997) II-1689 para. 57; Commission Decision of 14 July 1999, Case IV/D-2/34.780 – *Virgin/British Airways*, OJ L 30 (4.2.2001) p. 1, para. 92.

²³¹ Commission Decision of 20 June 2001, Case COMP/E-2/36.041 – *PO/Michelin*, OJ L 143 (31.5.2002) p. 1, para. 202.

²³² *Helmuth Schröter* in *Schröter/Jacob/Mederer* (Ed.), *Kommentar zum europäischen Wettbewerbsrecht*, 2005, Article 82, para. 74.

²³³ See for example Case 226/84, *British Leyland*, (1986) ECR 3263, para. 9; Case T-70/89, *ITP*, (1991) ECR II-535, para. 51; Case T-76/89, *ITP*, (1991) ECR II-575, para. 49; confirmed by Joined Cases C-241 and 242/91, *RTE and ITP*, (1995) ECR 743; Case T-229/94, *Deutsche Bahn*, (1997) ECR II-1689, para. 57, confirmed by Case C-437/97, *Deutsche Bahn*, (1999) ECR I-2387.

The pharmaceutical wholesalers rely on the supply of each of the pharmaceutical producers, not only because of the existing public service obligation but also because of the lack of substitutability on the wholesale level.

As explained already in connection with the market definition, a consequence of the public service obligation for wholesalers, which in some Member States even amounts to a legal obligation to keep the full range of products in stock, is that wholesalers constantly have to replenish their stocks so as to guarantee a balanced and sufficient supply of all pharmaceuticals.

Even if no legal obligation to keep the full range of products exists, it is in line with the character of the particular market that pharmaceutical wholesalers run the full range of products since otherwise they would put their economic existence at risk.²³⁴ Wholesalers cannot restrict themselves to the distribution of a group of specific therapeutic products or specific products of one manufacturer, but have to offer a broad spectrum of available products when supplying pharmacies and hospitals.

Furthermore, the public service obligation leads to the general assumption on the side of the doctors that a product is available in sufficient quantities at all times. Moreover, in comparison to pharmacists, wholesalers cannot fulfil orders placed by hospitals, clinics, pharmacies or other wholesalers by delivery of alternative products as the wholesaler is not allowed to substitute an ordered product.

In Germany, this assumption has been acknowledged by the German Federal Cartel Office (Bundeskartellamt) in a ruling in which it stated that every manufacturer of pharmaceuticals – with respect to its medicinal products – holds, vis-à-vis the wholesalers, a dominant position.²³⁵

2.5 *Conclusion*

In Article 82 EC cases concerning the distribution of pharmaceuticals and concerning a medicinal product that is still under patent protection one will in every case come to the conclusion that the pharmaceutical manufacturer is dominant.

In cases where the one product-one market approach is applied the pharmaceutical monopolist is consequently considered dominant vis-à-vis the wholesalers.

The same applies in cases where the relevant market is defined on the basis of therapeutic substitutability and no substitutable product exists on that market. The supplier then is a monopolist in a dominant position.

Only in cases where the relevant market is defined on the basis of therapeutic substitutability and comprises two or more substitutable products does one need to consider other factors. But even here one will come finally to the same result: the pharmaceutical undertaking has a dominant position towards the wholesalers.

This is mainly because, in limitation or refusal to supply cases, it becomes clear that the wholesalers depend on the pharmaceutical producers for the supply of products. From the viewpoint of the wholesalers, pharmaceutical undertakings are 'obligatory trading partners'. This dependence reflects dominance.

The high barriers to entry on a pharmaceutical product market, added to the economic strength and financial power of most of the pharmaceutical undertakings, support this assessment of dominance.

²³⁴ See also Commission Decision of 14 July 1999, Case IV/D-2/34.780 – Virgin/British Airways, OJ L 30 (4.2.2001) p. 1, para. 75, where the Commission notes that it is the nature of travel agency services to offer a full service line including air travel agency services.

²³⁵ Tätigkeitsbericht des Bundeskartellamtes, 1972, BT-Drucks. 7/986, p. 66 et seq.

The counter-argument of the pharmaceutical industry – i.e. that the single producer does not have pricing power and cannot therefore act independently because of the buyer power of the national regulatory systems – is to be rejected. It is not only the price which is important for the ability to behave independently on the market and to be able to restrict effective competition. Furthermore, the buyer power argument would only apply if the wholesalers that are affected by the alleged behaviour had any buyer power. This, however, is not the case.

3. Abuse

3.1 Introduction

Once a dominant position on a particular market is established the investigation can consider whether the market behaviour of the dominant player is abusive in the sense of Article 82 EC.

In particular business practices that are generally considered to be normal may constitute an abuse within Article 82 EC if they are carried out by an undertaking which holds a dominant position.

“The concept of an abuse is an objective concept referring to the conduct of an undertaking in a dominant position which is such as 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 already weakened and which, through recourse to methods different from those governing normal competition, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.”²³⁶

In short, the test in *Hoffmann-La Roche* sets out that a behaviour is abusive if it is not based on competition on the merits and if its effect is hindering the maintenance or growth of competition. Dominant undertakings thus have a special responsibility²³⁷ to avoid any measures that could be held abusive in the sense of *Hoffmann-La Roche*.

Since *United Brands* it is also a well-known principle that an undertaking with a dominant position has a right to protect its own commercial interests. Practices supposed to protect commercial interests, however, have been subject to the reservation that they do not go beyond the legitimate and proportionate protection of their interests²³⁸:

“Whilst the fact that an undertaking is in a dominant position cannot disentitle it from protecting its own commercial interests if they are attacked and whilst such an undertaking must be conceded the right to take such reasonable steps as it deems appropriate to protect its said interests, such behaviour cannot be countenanced if its actual purpose is to strengthen this dominant position and abuse it.”²³⁹

Several examples of such behaviour have been subject to detailed analysis by the ECJ in respect of Article 82 EC. It would go beyond the scope of this paper to establish the general principles for all of them in detail. Therefore, the paper confines itself to the practices of the pharmaceutical industry at stake, namely the limitation or refusal to supply.

²³⁶ Case 85/76, *Hoffmann-La Roche*, (1979) ECR 461, para. 91.

²³⁷ Case C-395/96 P, *Compagnie Maritime Belge v Commission*, (2000) ECR I-1365, para. 114.

²³⁸ Case 27/76, *United Brands v Commission*, (1978) ECR 207, para. 189.

²³⁹ Case T-65/89, *BPB Industries Plc and British Gypsum*, (1993) ECR II-389, para. 69.

The following chapter will therefore show that a limitation or refusal to supply wholesalers to prevent parallel distribution can be neither held to be competition on the merits nor a behaviour that can be justified with a legitimate interest.

3.2 *Categorisation of the initiatives of the pharmaceutical industry*

Before analysing the case law on refusal to supply and supply limitations it seems necessary to establish again precisely the types of abusive behaviour of the pharmaceutical undertakings and what effects these have on the market.

The limitation or refusal to supply is directed against wholesalers in the export country to prevent them from selling products to wholesalers in the import country. Accordingly, in the export country market the behaviour of the pharmaceutical industry is primarily directed against their customers.

In the import country parallel distributed medicines compete with the products that are placed directly on the import market by the pharmaceutical undertaking. One could, therefore, also assume that a refusal to supply the export wholesaler is directed against a potential or actual competitor for the supply of pharmaceuticals to wholesalers (including importers) in the import country.

The effect is twofold.²⁴⁰ On the one hand it prevents competition on the downstream market between the wholesalers in each individual export country, but also between wholesalers and distributors of different export countries. On the other hand importing distributors are indirectly prevented from competing with other wholesalers in the import country in offering cheaper alternatives. Therefore, the decision to supply or not gives the pharmaceutical industry the possibility to control and bias competition between wholesalers.

At the same time the pharmaceutical industry protects its own products from intra-brand competition²⁴¹ in the import country by refusing to supply wholesalers in the export country that engage in intra-community distribution. It is a natural and foreseeable consequence – given also the public service obligation of the wholesalers – that wholesalers are likely to withdraw from any export activity when they do not receive sufficient quantities. At the same time this strengthens the bargaining power of the pharmaceutical industry in the negotiations about prices and reimbursement levels for their products in the import country.

The latter factual situation shows similarities to the classic situation where an undertaking uses its dominant position in an upstream product market to prevent competition on a downstream product market. Instead of different product markets the pharmaceutical industry uses its dominant position in one geographic market to prevent competition in another geographic market. While each individual pharmaceutical company does not compete with the wholesalers on the market for the distribution of a pharmaceutical in the export market, there is competition on that market in the import country.

²⁴⁰ Therefore the assumption of EFPIA (Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004 p. 59) on the effects of a refusal to supply are misleading.

²⁴¹ Although parallel distributed pharmaceuticals must have a different brand name in some of the importing countries one can consider the competition between the products in the import market in general as intra-brand competition and not as inter-brand competition. In difference to other identical products with different brands that would compete on the inter-brand level in view of the consumer, the different product name for pharmaceuticals has no such effect. Doctors and pharmacists generally know that a parallel distributed product is identical with the original when they decide to dispense it.

3.3 Aim of competition policy – intra-brand competition and single market imperative

It is appropriate at this point to recall the aims of EC competition policy. Cases where a refusal to supply is aimed at or has the effect of preventing parallel distribution have to be assessed in particular against the background of these aims.

Competition law in general aims to maximise consumer welfare by achieving the most efficient allocation of resources.²⁴² Part of this exercise is consumer protection and the prevention of any weakening of competition on the market.

European competition law fulfils, however, an additional function. It forms part of the measures established by the EC Treaty to achieve a single market. EC competition rules therefore pursue the basic aim of the EC Treaty to eliminate commercial barriers between Member States and are thus directed against any measures from undertakings which would reconstruct such barriers.²⁴³

Intra-brand competition between wholesalers as well as between retailers of different Member States is a particular feature of the single market. Intra-brand competition is commonly known as competition of distributors and of retailers in relation to the products of one firm.²⁴⁴ If this competition takes place between distributors and/or between wholesalers of different Member States it contributes to the completion of the single market.

Accordingly, EC competition rules aim to prevent the reduction of intra-brand competition between distributors if it leads to a division of national markets and, therefore, prohibit absolute territorial protection.²⁴⁵ This is based on the principle that the European consumer should be able to buy goods from the cheapest source anywhere in the EU.²⁴⁶

The significance of protection of intra-brand competition within the EU becomes clear in particular with regard to intellectual property rights. While in general trademarks, patents or other intellectual property rights grant a national monopoly to the owner of that right, owners cannot rely on the national exclusivity within the EU.²⁴⁷ The principle of exhaustion, which allows for the free circulation of a product once it is lawfully placed on the market in one Member State, prevents the foreclosure of national markets and aims to enhance intra-brand competition throughout the EU. It also shows that particularly where inter-brand competition is limited because of the exclusivity granted by intellectual property rights, intra-brand competition is a vital component of the single market and needs to be protected.²⁴⁸

Furthermore, it is explicitly mentioned in the guidelines on vertical restraints under Article 81 EC that intra-brand competition needs to be protected.²⁴⁹ Even in exclusive dealing agreements, which de facto allow for a separation of markets, a producer cannot prohibit the passive sale of his products into another protected area.²⁵⁰ Moreover, the prohibition of active sales to other protected areas is only exempted in exclusive agreements as long

²⁴² *Richard Wish*, *Competition Law*, 2003, p. 17.

²⁴³ Case 56 u. 58/64, *Consten and Grundig*, (1966) ECR 299, 340; see also Commission Decision of 8 May 2001, Case IV/36.957/F3 – *Glaxo Wellcome*, OJ L 302 (17.11.2001) p. 1, para. 130: "(...) competition rules equally aim at preventing the partitioning of the common market along national lines."

²⁴⁴ Commission notice, *Guidelines on vertical restraints*, OJ C 291 (13.10.2000) p. 1, para. 6.

²⁴⁵ Commission notice, *Guidelines on vertical restraints*, OJ C 291 (13.10.2000) p. 1 para. 103.

²⁴⁶ *Bellamy and Child*, *European Community Law of Competition*, 2001, para. 1-078.

²⁴⁷ Case 187/80, *Merck v. Stephar*, (1981) ECR 2603; Case C-191/90, *Generics and Harris Pharmaceutical*, (1992) ECR I-5335, Joined Cases C-267/95 and C-268/95, *Merck v. Primecrown*, (1996) ECR I-6285.

²⁴⁸ Case 238/87, *Volvo/Veng*, (1988) ECR 6211, para. 9; T-198/98, *Micro Leader Business*, (1999) ECR II-3989, para. 55.

²⁴⁹ Commission notice, *Guidelines on vertical restraints*, OJ C 291 (13.10.2000) p. 1, para. 6.

²⁵⁰ Article 4 b) of Regulation 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices, OJ L 336 (29/12/1999) p. 21.

as the parties of the agreement have a market share below 30%.²⁵¹ One can therefore conclude that a restriction of intra-brand competition that leads to a national market foreclosure is only acceptable for as long as the company implementing this strategy has no substantial market power.

This conclusion has been contested by the pharmaceutical industry. It has argued that the practical effect of a unilateral refusal to supply resembling a violation of Article 81 EC does not mean that there has been a violation of Article 82 EC.²⁵² This is only true as long as the company acting is not dominant and does not abuse its position to achieve the same effect. The argument ignores the fact that, if the prerequisites of Article 82 EC are fulfilled, e.g. the company is dominant on a particular market, and its refusal to supply has the effect of hindering competition Article 82 EC has to apply. Whether a prevention of intra-brand competition is achieved by an agreement or by a unilateral act of a dominant firm abusing its position on the market is irrelevant.

The case law itself shows that Article 82 EC indeed aims to protect intra-brand competition.²⁵³ Moreover, the idea behind a rule such as Article 82 EC is to protect intra-brand competition. It is already inherent in the concept of dominance that there is mainly scope for intra-brand competition on a downstream level since in a market with a dominant undertaking inter-brand competition is always limited if not excluded.

Accordingly, in the presence of a distortion of intra-brand competition that in addition leads to a division of national markets – due to either an agreement or a company's unilateral actions – competition rules have to be applied. An interpretation of Article 82 EC has to take into account that dominant companies cannot undermine the freedoms guaranteed to the market participants by the EC Treaty.²⁵⁴

3.4 *Refusal to supply and supply limitations – the categorisation of the case law*

The case law of the ECJ and subsequent commentators categorise cases of refusal to supply into different groups based on factual circumstances. Broadly one can distinguish cases of refusal to supply an existing customer from cases involving a new customer.

Furthermore, when analysing a refusal to supply or a supply limitation vis-à-vis a customer, one needs to make a distinction between cases of a pure supplier- customer relationship and cases where the customer is an actual or potential competitor of the supplier.

As explained above in cases where the pharmaceutical industry is refusing to supply a wholesaler in the export country in order to prevent parallel distribution of the products in question, the wholesaler is first of all a customer of the pharmaceutical producer.

Even if there is no general obligation for any business, even if it is dominant, to enter into a particular contract with a third party²⁵⁵ the circumstances can oblige an undertaking to contract or to continue to supply. These circumstances will be set out further below (see section 3.5 and 3.6).

²⁵¹ Article 3 of Regulation 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices, OJ L 336 (29/12/1999) p. 21.

²⁵² EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?, 2004, p. 62.

²⁵³ Case 226/84, *British Leyland v Commission*, (1986) ECR 3263, para. 16, 21 and 24; Case 27/76, *United Brands*, (1978) ECR 207, para. 130/138, 152/160.

²⁵⁴ *Christian Koenig, Christina Engelmann*, Parallel trade restrictions in the pharmaceutical sector on the test stand of Art. 82 EC: Commentary on the opinion of Advocate General Jacobs in the Case Syfait/GlaxoSmithKline, ECLR 2005, 338.

²⁵⁵ *Romano Subitto, Robert O'Donoghue*, Defining the scope of dominant firms to deal with existing customers under Article 82 EC, ECLR 2003, 683; *Bellamy and Child*, European Community Law of Competition, 2001, para. 9-902.

Normally, one would not consider it to be a rational economic or business response for a company to refuse to supply its products. The arguments presented by the pharmaceutical industry to explain their behaviour will therefore be carefully scrutinised (see section 3.7).

As set out above, in cases where wholesalers also engage in intra-community distribution and the parallel distributed products compete with the original products in the import country, the pharmaceutical undertaking is *de facto* refusing to supply an actual or potential competitor. However, the factual circumstances are different from the case law which concerns the abusive character of refusals to supply a competitor established first by *Commercial Solvents*.²⁵⁶ These cases dealt primarily with a restriction of inter-brand competition and not intra-brand competition. The terms and prerequisites established by this case law for the assessment of an abusive character of a refusal to supply with regard to a competitor cannot be transferred to the cases at stake.²⁵⁷

The same applies to the essential facilities doctrine. This doctrine sets out the conditions that must be fulfilled to oblige a dominant company to supply its customers or to give them access to its products or services to allow competition on a downstream market.

However, there is a significant qualitative difference between the cases discussed here and the cases of refusal of access to products or services covered by the essential facilities doctrine.²⁵⁸ The application of the essential facilities doctrine demands

*"(...) scope for substantial non-price competition on the [downstream] market, that is, it is not merely simple resale or distribution of products or services, and a refusal to contract would prejudice consumers."*²⁵⁹

The application of this doctrine requires therefore that added value is generated on a downstream market with the help of the upstream product in the form of a derivative product. Thus the added value cannot be achieved by a mere resale.

In the distribution of pharmaceuticals there is no such added product-related value since the products acquired by the wholesalers do not become a different product as a result of resale or the export/import process. Nor does possible repackaging or the adding of new information leaflets change the product as such.

Accordingly, the following analysis will focus only on the assessment of cases in which the refusal to supply is directed against a customer of the dominant undertaking, namely against the pharmaceutical wholesalers in the export countries.

3.5 *Intention to foreclose national markets - a per se abuse*

Cases in which the intention to limit parallel distribution is obvious can only be held abusive in the sense of Article 82 EC be it that the pharmaceutical undertaking admits its anti-competitive intention like in *Syfait*²⁶⁰ or that it becomes evident from its behaviour. It is

²⁵⁶ Cases 6/73 and 7/73, *ICI and Commercial Solvents v Commission*, (1974) ECR 223, para. 33.

²⁵⁷ Similar to the essential facilities doctrine the cases on refusal to deal a competitor require the input that is refused to be essential for the competition on the downstream market, in the sense that it cannot be duplicated or only be duplicated at uneconomic costs. This concept, however, is based on the assumption of two different product markets. In case of intra-brand competition there is no such two different product markets. Further, intra-brand competition does not aim to duplicate the input but to lead to more competition in the distribution of the input.

²⁵⁸ *Christian Koenig, Christina Engelmann*, Parallel trade restrictions in the pharmaceutical sector on the test stand of Art. 82 EC: Commentary on the opinion of Advocate General Jacobs in the Case *Syfait/GlaxoSmithKline*, ECLR 2005, p. 338, 339.

²⁵⁹ *Temple Lang*, Anticompetitive Non-Pricing Abuses Under European And National Antitrust Law, in: Hawk (ed.), *International Antitrust Law & Policy*, Fordham Corp. L. Inst. (2004) p. 235, 270.

²⁶⁰ Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 71.

evident from the case law of the ECJ that a refusal to supply amounts to an abuse *per se* if it is intended to foreclose national markets in particular by limiting parallel distribution.

- In *British Leyland*, the ECJ deemed unilateral measures by a dominant company with the intention to prevent the re-importation of cars to be abusive within the meaning of Article 82 EC. The classification as abuse was based solely on the fact that the measures concerned were an expression of the clear intention to create barriers to re-importations.²⁶¹
- In *United Brands* the ECJ held that an artificial partitioning of the market with the effect of hindering the free movement of goods was abusive.²⁶² In this case bananas were sold on a discriminatory price base. Additionally, it was forbidden to resell bananas while they were still green. Since ripe bananas are difficult to transport the later prohibition led in fact to a foreclosure of national markets.
- In *Irish Sugar* the foreclosure of a national market was the result of a price policy that effectively prevented imports of sugar from North-Ireland to Great Britain. The ECJ held that such an obstacle to the achievements of the common market is *per se* abusive if undertaken by a dominant player.²⁶³
- Similarly, in *AAMS/Commission* the Court held that measures intended to prevent imports of cigarettes from other Member States amounted to an abuse under Article 82 EC.²⁶⁴

A different view has been expressed lately by Advocate General Jacobs in *Syfait*. His analysis of the case law led him to the conclusion that even the intention to limit parallel distribution would not necessarily lead to an abuse *per se*.²⁶⁵ The conclusion, however, is based on debatable assumptions.

First, most of the case constellations that Advocate General Jacobs analysed did not contain a reference to an intentional foreclosure of national markets.²⁶⁶ Cases that refer to an intentional foreclosure of markets have either been neglected or stated incompletely. Moreover, nearly half of the cases presented by the Advocate General were cases based on the essential facility doctrine which – as explained above - cannot be equally applied to the cases in question. Further, in the Advocate General's view, the partitioning of the market was not a primary intent of GSK but an "*inevitable consequence*" of the market characteristics and therefore open to justification.²⁶⁷ However, as it will be shown below, the particular market characteristics in the pharmaceutical sector cannot justify the anticompetitive behaviour of pharmaceutical producers if it is intended to prevent parallel distribution.

Consequently, the opinion of the Advocate General, when scrutinised carefully, is not convincing and fails to rebut the principles established by the existing case law. All of the judgements cited above show that measures by dominant companies aimed at preventing exports of their products to protect them from inter-brand or intra-brand competition in other national markets within the EU are classified as abusive *per se*. Such measures are contrary to the principle of market integration enshrined in the EC Treaty. Accordingly, a

²⁶¹ Case 226/84, *British Leyland v Commission*, (1986) ECR 3263, para. 16, 21 and 24.

²⁶² Case 27/76, *United Brands*, (1978) ECR 207, para. 130/138, 152/160; *Bellamy and Child*, European Community Law of Competition, 2001, para. 9-084.

²⁶³ Case T-228/97, *Irish Sugar v Commission*, (1999) ECR II-2969, para. 185.

²⁶⁴ Case T-139/98, *Amministrazione Autonoma dei Monopoli di Stato (AAMS) v Commission*, (2001) ECR II-3413, para. 94 et seq.

²⁶⁵ Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 53.

²⁶⁶ For instance: C-7/97, *Bronner*, (1998) ECR I-7791, para. 9 (capacity problems) ; joined Cases C-241/91P and 242/91P, *RTE and ITP v Commission*, (1995) ECR I-743, para. 34 (intellectual property rights).

²⁶⁷ Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 71.

refusal to supply always constitutes an abuse of a dominant undertaking if it aims to foreclose national markets to protect the company's market position.²⁶⁸

Applying this basic principle to the cases at stake inevitably leads to the conclusion that any refusal or limitation to supply that is intended to prevent the parallel distribution of pharmaceuticals must be viewed as an abuse *per se*. Consequently, such behaviour is not open to justification or proportionality considerations. There is no such argument that could justify an intentional foreclosure of the market.

3.6 *Refusal to supply and limitation to supply a customer that is not abusive per se*

Cases of refusal to supply wholesalers that are not considered abusive *per se* need to be analysed in the context of the case law established by the ECJ and the Commission's practice with regard to refusals to supply customers.

(a) *The United Brands test*

In *United Brands* the ECJ held that a dominant undertaking cannot stop supplying a long standing customer who abides by regular commercial practice if the orders placed are in no way out of the ordinary.²⁶⁹ While the immediate focus usually lies on the second part of this quote, one tends to overlook the importance of the first. Moreover, this first half plays a crucial role in how one interprets the second half.

The Court refers to a regular commercial practice. The cross-border distribution of products is a regular commercial practice which is actively promoted in the EU by the principle of free movement of goods. As explained above, pharmaceuticals are included in the application of that principle.²⁷⁰ Accordingly, wholesalers selling pharmaceuticals to wholesalers in other Member States carry out a regular and legal commercial activity that is protected by EC law.

The second test, inherent in *United Brands*, is the question of whether or not the orders placed by the customer are "out of the ordinary". Needless to say, the verification of what amounts to an "ordinary order" must be established by objective criteria and is subject to the proportionality test. It is, however, important to note in this respect that orders that include products to be distributed into other Member States are in general not "out of the ordinary" since the cross-border distribution is an accepted commercial practise.

With regard to pharmaceutical products, the evaluation of what constitutes an "ordinary order" will also need to take into account the public service obligation imposed on wholesalers and pharmaceutical producers. However, the public service obligation as such does not in itself determine the scope of an "ordinary order".²⁷¹ On the contrary, the public service obligation has to be interpreted as the necessary minimum requirement that needs to be met.

If wholesalers locate additional sales markets within and outside their national territory which they can supply within their regular commercial practise, such activities cannot be deemed "out of the ordinary". Otherwise one would need to conclude that any wholesaler, whether dealing with pharmaceuticals or with other products, that finds additional sales markets and wants to supply them, can be obstructed in his commercial activities by the producer.

²⁶⁸ Christian Koenig, Christina Engelmann, Parallel trade restrictions in the pharmaceutical sector on the test stand of Art. 82 EC: Commentary on the opinion of Advocate General Jacobs in the Case Syfait/GlaxoSmithKline, ECLR 2005, p. 338, 339 with further references.

²⁶⁹ Case 27/76, *United Brands v Commission*, (1978) ECR 207, para. 182/183.

²⁷⁰ Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, COM (2003) 839, p. 6.

²⁷¹ This has been suggested by EFPIA: Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004, p. 63.

It becomes obvious from *United Brands* that the Court assumes that a refusal to supply orders which are not out of the ordinary is in general capable of limiting the market at the expense of the consumer and would amount to discrimination which might in the end eliminate a trading partner.²⁷²

As explained above this conclusion can also be drawn with regard to a refusal to supply pharmaceutical wholesalers. The adverse effect of a refusal to supply becomes clear if one considers, in the cases at stake, the risk that the wholesalers cannot fulfil their public service obligation and accordingly an adequate supply of pharmaceuticals to the consumer is as such not guaranteed.²⁷³ Second, there is an effect which is to the detriment of the distribution system which would be less effective and efficient, and would force consumers (pharmacies or hospitals) to find different sources of supply of the requested products. And, above all, the financial benefits for consumers and national health care systems would cease to exist (see chapter II, section 6).

Accordingly, a refusal to supply wholesalers which order pharmaceuticals not “out of the ordinary” is abusive. Thereby, any consideration of what constitutes an ordinary order has to be established on objective criteria and cannot be based exclusively on the quantity of products necessary to fulfil the public service obligation.

(b) *Refusal to supply as a disciplinary measure*

A further aspect that needs to be considered in this respect is the motivation that is inherent in the refusal to supply or supply limitation. The case law shows that a company using its market power to discipline or threaten distributors with a view of foreclosing the market is equally engaging in abusive behaviour within the meaning of Article 82 EC.

In *United Brands* the refusal to supply was intended to prevent the distributor from selling competitor's products; in *BBI/Boosey and Hawkes*²⁷⁴ the intention was to penalise a distributor who promoted a competing brand; in *Polaroid/SSI Europe*²⁷⁵ the refusal to supply was intended to prevent further processing and marketing of the products without the dominant undertakings control, thus, forcing the distributor to reveal its customers. All these measure were held to be abusive.

As set out above, in the cases at stake, the pharmaceutical undertakings intend to protect their products from intra-brand competition in the import market. The refusal to supply products that could potentially be parallel distributed is, thus, no different from a disciplinary measure to secure the market position of the pharmaceutical undertakings in the import country.

The pharmaceutical undertakings use their market power, and in particular the fact that the wholesalers are dependent on their deliveries, to put pressure on the wholesalers. In addition, the pharmaceutical undertakings misuse the public service obligation for the wholesalers to further their own interests. They thereby induce their customers to adopt a particular course of action which in practice is likely to lead to a foreclosure of intra-brand competition.

Accordingly, in all cases where it becomes obvious that a limitation or refusal to supply is intended to exert influence on the distribution behaviour of the wholesalers, such a refusal has to be held to be abusive.

²⁷² Case 27/76, *United Brands v Commission*, (1978) ECR 207, para. 182/183.

²⁷³ In *Syfait* the Greek Competition Authority found that shortages had only occurred after the manufacturer had introduced supply restrictions.

²⁷⁴ Commission Decision of 29 July 1987, Case IV/32.279 – *BBI/Boosey & Hawkes*, OJ L 286 (9.10.1987) p. 36, para. 19 et seq (promotion of a competing brand).

²⁷⁵ Thirteenth Report on Competition, Commission of the European Communities, 1983, p. 95.

(c) *Discriminatory refusal to supply*

A refusal to supply will frequently be abusive if it is discriminatory. Being dominant, the pharmaceutical undertakings have to apply a non-discriminatory supply policy towards their wholesalers. This does not only apply to the existing wholesalers that have to be supplied on non-discriminatory conditions. Whenever a new wholesaler wants to enter the market for the supply of pharmaceutical products, the pharmaceutical producer has to apply similar conditions as for existing wholesalers. This is due to the position of pharmaceutical producers as obligatory trading partners. The Commission has noted that:

"(...) abuse within the meaning of article 8[2] of the Treaty may be defined as any action of an undertaking in a dominant position which reduces supplies to comparable purchasers in different ways without objective justification, and thereby puts certain of them at a competitive disadvantage to others, particularly where such action can result in changes in the structures of the particular market."²⁷⁶

The ECJ observed that, even in the time of product shortages, the undertaking may lay down the criteria for the priority in which orders are met, but they must be objectively justifiable and may not be discriminatory in any way.²⁷⁷ Accordingly, the Court held that an undertaking is not permitted to favour customers that exclusively deal with it over those also dealing with competitors. Similarly, an undertaking cannot favour customers that only engage in national trade to those also dealing across borders.

(d) *Conclusion*

The alternatives set out above demonstrate that, irrespective of the factual circumstances, a refusal to supply that aims to impede parallel distribution, and thus to create a foreclosure of national markets, can only be held to be abusive.

Such a refusal to supply leads in effect to a weakening of competition in the downstream market for the supply of pharmaceuticals.

3.7 *Justification and Proportionality*

The theoretical possibility might exist that, in certain cases, a refusal to supply wholesalers with the intention to prevent parallel distribution of pharmaceuticals could be open to justification. However, there have so far been no arguments established that could prevail.

With regard to refusals to supply by the pharmaceutical industry this question has in particular been discussed by Advocate General Jacobs in *Syfait*.²⁷⁸ In his view the following aspects need to be considered when considering the liability of a dominant pharmaceutical undertaking for a refusal to supply:

"(...) first, the pervasive regulation of price and distribution in the sector; secondly, the likely impact of unmoderated parallel trade upon pharmaceutical undertakings in the light of the economics of the sector; and thirdly, the effect of such trade upon consumers and purchasers of pharmaceutical products."²⁷⁹

These aspects will be scrutinised carefully in the following chapter, considering that a refusal to supply can only be justified by technical or commercial requirements that leave the company no other choice than to reduce its deliveries²⁸⁰.

²⁷⁶ Commission Decision of 16 April 1977, Case IV/28.841 ABG/Oil Companies, OJ L 117 (9.5.1977) p. 1

²⁷⁷ Case T-65/89, *BPB Industries Plc and British Gypsum*, (1993) ECR II-389, para. 46.

²⁷⁸ Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 73 et seq.

²⁷⁹ Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 76.

²⁸⁰ Case 311/84, *CBEM/CLT and IPB*, (1985) ECR 3261, para. 26.

It is however important to note that the burden of proof for any justification of a supply restriction or refusal to supply lies with the pharmaceutical undertakings.²⁸¹ This has also been confirmed by the Advocate General in *Syfait* stating that the conditions for an objective justification have to be "*demonstrated*".²⁸²

(a) *State regulation*

It has been argued that the regulation of pharmaceutical prices in particular and the national reimbursement systems in general can justify measures taken by the pharmaceutical producers to prevent the export of their products.²⁸³

This argument is based on the assumption that because of national price and reimbursement regulation the pharmaceutical companies are on the one hand forced to agree on prices that they would preferably set differently and on the other hand that the national regulation of prices and reimbursement levels prevents the industry from intervening in intra-brand competition by price competition.²⁸⁴

(i) *State regulation does not prevent the application of general principles of the EC Treaty*

First of all, national market regulation does not prevent the application of the general principles of the EC Treaty. Even if the main incentive for parallel distribution of pharmaceuticals results from the diverging regulating systems in the Member States the ECJ has repeatedly set out with regard to Article 28 EC that it is

*"a matter of no significance that there exist as between the exporting and importing Member States, price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product"*²⁸⁵

Accordingly, the ECJ applied the principle of free movement of goods and, as set out above, has protected parallel distribution of pharmaceuticals from any attempt by national law to prevent it.

The same principle has to apply with regard to the application of EC competition law. National price regulation cannot justify any exception from the application of competition rules. The argument that the prevention of parallel trade only eliminates the competition distortions which result from diverging state regulations, cannot be taken into consideration either within the application of Article 28 EC or within the application of Article 82 EC.²⁸⁶

With regard to Article 81 EC the Commission has already clarified that:

²⁸¹ Case T-228/97, *Irish Sugar v Commission*, (1999) ECR II-2969, para. 189; Case T-139/98, *AAMS/Commission*, (2001) ECR II-3413, para. 79 and 95.

²⁸² Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 72.

²⁸³ See e.g. recently: *Erwin Krapf, Dr. Barbara Lange*, Staatliche Interventionen, duale Preissysteme und europäisches Kartellrecht, PharmR 2005, p. 255, 265.

²⁸⁴ See also: Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 77 et seq.

²⁸⁵ Case 15/74, *Centrafarm v. Sterling*, (1974) ECR 1147; Case 16/74, *Centrafarm and De Peijper v. Winthrop*, (1974) ECR 1183.

²⁸⁶ *Christian Koenig, Christina Engelmann*, Parallel trade restrictions in the pharmaceutical sector on the test stand of Art. 82 EC: Commentary on the opinion of Advocate General Jacobs in the Case *Syfait/GlaxoSmithKline*, ECLR 2005, p. 338.

*"(...) there is no reason why Community law should permit undertakings to restrict the free movement of such goods by means of private law contracts where the conditions of Article 81(1) are met."*²⁸⁷

Similarly there is no reason why Community law should permit undertakings to restrict the free movement of goods by abusive means where the conditions of Article 82 EC are met. In principle that has already been stipulated by the ECJ with regard to different national tax rules in *Volkswagen*.

In this case the ECJ did not accept different national tax regulations as a justification to restrict the parallel distribution of motor vehicles. It expressly ruled that the lack of harmonisation in the tax regulation does not release the manufacturers from their obligation to observe the main rules of the single market including the prohibition on market foreclosure.²⁸⁸

(ii) *State regulation does not prevent the pharmaceutical industry to influence the price setting*

Moreover, it is important to note that, despite regulatory systems, the pharmaceutical undertakings have an influence on the price and reimbursement settings. As seen above (see chapter II, section 2.2) companies can either suggest prices or at least negotiate the price for their products to a substantial part.

This is also what distinguishes the area of pharmaceutical regulation from the above mentioned case on tax regulation. In tax regulation there is no scope for the undertakings to influence the regulation, and yet even they cannot rely on the different national systems to justify their behaviour. Accordingly, it is not conceivable that pharmaceutical undertakings, which have direct influence on the regulation in each individual case, should be able to justify their anti-competitive behaviour by relying on the nature of the different national regulatory systems.

(iii) *State regulation does not allow undertakings to use anticompetitive measures in the absence of harmonization*

The fact, that price and reimbursement regulation prevents the pharmaceutical industry from intervening in the intra-brand competition by price competition cannot in turn lead to the conclusion that it allows to use other anticompetitive measures.

Dominant undertakings are only allowed to compete on the merits. If price competition is fully or partially excluded because of regulatory mechanisms, then pharmaceutical undertakings have to find other merits they can compete with.

After all, if dominant companies were allowed to combat parallel distribution, this would not eliminate the obstacles to the free market based on diverging national price regulations, but rather reinforce them. If competition alone is not sufficient to eliminate price differences caused by regulatory measures in the long term, the corresponding regulations must be harmonised at European level. The ECJ has set out in this respect:

*"It is well settled that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules on free movement of goods."*²⁸⁹

²⁸⁷ Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001), p. 1, para. 129.

²⁸⁸ Case T-62/98, *Volkswagen I* (2000) ECR II-2707 para. 336.

²⁸⁹ Joined Cases C-267/95 and C-268/95, *Merck v Primecrown*, (1996) ECR I-6285, para. 47.

Until then, however, complete compliance with the EC competition rules must be ensured in order to avoid setbacks to the process of integration.²⁹⁰ And where measures of Member States are incompatible with the rules on free movements of goods, the same must apply to measures of undertakings aiming to eliminate parallel distribution resulting from price differences in the various Member States. Such measures of undertakings are anti-competitive and not to be tolerated under the rules of the EC Treaty.

Even in areas in which state regulation exists, it is the task of the competition rules to protect the remaining competition and to prevent any reinforcement of existing single market obstacles by corporate practices.²⁹¹

(iv) *Conclusion*

The national regulation of pharmaceutical markets within the EU leads to different market conditions that influence the behaviour of the market participants. However, the regulation of pharmaceutical prices and reimbursement levels does not exclude the application of Article 82 EC.

On the contrary, the competition rules in general and Article 82 EC in particular have the main task to protect the remaining competition since even though state regulation exists there is enough scope for the industry to influence the regulatory parameters in each individual case and enough scope for competition on other parameters than price.

National price and reimbursement regulation therefore cannot be used by the pharmaceutical industry to justify any anti-competitive behaviour, in particular refusals to deal.

(b) *Negative impact on R&D budgets*

The second consistently repeated argument to justify refusals to supply of pharmaceuticals is the alleged negative impact of parallel distribution on R&D budgets.²⁹²

While in general it is assumed that a duty to deal can reduce the incentive to innovate, the actual risk would need to be assessed on a case to case basis and would need to be based on sustainable evidence.

As explained in detail above (see chapter II, section 4.4) so far there is no conclusive evidence for any negative impact of parallel distribution of pharmaceuticals on R&D budgets. On the contrary, statistics show that the pharmaceutical industry acts profitably despite higher R&D costs and expenditure and despite parallel distribution of their products.

The only impact parallel distribution has is an impact on the profits of the pharmaceutical industry which is relatively small. However, a reduction in the company's profits cannot in itself justify abusive anti-competitive practices.²⁹³

Accordingly, the argument that aims to make parallel distribution responsible for lower R&D budgets cannot be used as justification for any refusal to supply.

²⁹⁰ Communication from the Commission, A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient: A Call for Action, COM (2003) 383 final, p. 16.

²⁹¹ For the significance of the protection of remaining competition on highly regulated markets also ECJ, Joined Cases 209-215 and 218/78, *FEDETAB*, (1980) ECR 3125, para. 131.

²⁹² Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 89 et seq.

²⁹³ See Commission Decision of 8 May 2001, Case IV/36.957/F3 – Glaxo Wellcome, OJ L 302 (17.11.2001), p. 1, para. 156.

(c) *Consumer interest*

The argument that parallel distribution is of no benefit to either the ultimate consumers of pharmaceutical products or the Member States' health systems²⁹⁴ is incorrect in two regards.

First, it is not backed by facts. As explained in detail above parallel distribution benefits the consumers in different ways, both in the import and in the export country. (see chapter II, section 6.).

Second, it is generally misplaced as an argument for the justification of supply restrictions or limitations. Any justification of restrictions of parallel distribution must not be measured on the putative benefits of the parallel distribution, but on the benefits of the restrictive measure.

Accordingly, it would be necessary for the pharmaceutical undertaking to show, that parallel distribution of pharmaceuticals is harmful for consumers. Only then would prevention of parallel distribution be in the consumer interest,²⁹⁵ e.g. if it would be impossible for pharmaceutical companies to organise their manufacturing and sales processes in an economically feasible manner and in conformance with the valid regulations.²⁹⁶

In addition to this, the question concerning the social value of parallel distribution is irrelevant because it calls into question the system of free movement of goods and thus the EU single market itself.²⁹⁷ As seen above, it is the aim of competition law to support the achievements of the common market and protect intra-brand competition.

The fear that parallel distribution would stop pharmaceutical companies from selling their products in so-called "low-price countries" and would make them reluctant to place new products on the market is speculative and should be dismissed completely in the light of the facts ruling the pharmaceutical market. As shown above, it is to assume that marketing delays in some of the low price countries are attributed to the intention of the pharmaceutical industry to reach a high market price since it is usually the countries that operate a cross-country reference pricing that have to cope with such delays.

Even if any such trend of marketing delays due to parallel distribution became apparent, it would be the task of the national and European legislators to introduce the corresponding regulatory safeguards and not the companies themselves to assume protective measures.

(d) *Other arguments*

Other grounds for justifying refusals to supply have already been articulated in the course of the ongoing discussion. Some of them shall be briefly commented on here.

- Capacity problems

Possible capacity problems are a first argument. But such problems seem to be highly unlikely. The pharmaceutical industry would need to prove that they were unable to satisfy the needs of the wholesalers.²⁹⁸ In doing so, one would need to consider the

²⁹⁴ Opinion of Advocate General Jacobs from 28 October 2004 in Case C-53/03 *Syfait*, para. 96 et seq.

²⁹⁵ Case T-228/97, *Irish Sugar v Commission*, (1999) ECR II-2969, para. 188 and 189.

²⁹⁶ *Christian Koenig, Christina Engelmann*, Parallel trade restrictions in the pharmaceutical sector on the test stand of Art. 82 EC: Commentary on the opinion of Advocate General Jacobs in the Case *Syfait/GlaxoSmithKline*, ECLR 2005, p. 338.

²⁹⁷ *Christian Koenig, Christina Engelmann*, Parallel trade restrictions in the pharmaceutical sector on the test stand of Art. 82 EC: Commentary on the opinion of Advocate General Jacobs in the Case *Syfait/GlaxoSmithKline*, ECLR 2005, p. 338.

²⁹⁸ Cases 6/73 and 7/73, *ICI and Commercial Solvents v Commission*, (1974) ECR 223, para. 28.

capacity of the pharmaceutical undertaking as a whole and not only its national subsidiary.²⁹⁹

- No protection of competitors

The argument that a company is not obliged to protect its competitors is an argument drawn basically only in inter-brand competition cases. As already explained, cases of intra-brand competition are based on a different factual situation. Wholesalers in the export country are primarily customers and the competition that needs to be protected is the competition between these customers for the distribution of pharmaceuticals within the EEA.

Even if one assumes that wholesalers are competitors, an obligation to supply is not intended to protect the wholesalers as such but to protect the intra-brand competition.

- Right to protect commercial interests

A further argument presented to justify limitations or refusals to supply is the legitimate right of an undertaking to protect its commercial interests.³⁰⁰ The ECJ clarified in this respect that:

"Although it is true, as the applicant points out, that the fact that an undertaking is in a dominant position cannot disentitle it from protecting its own commercial interests if they are attacked, and that such an undertaking must be conceded the right to take such reasonable steps as it deems appropriate to protect its said interests, such behaviour cannot be countenanced if its actual purpose is to strengthen this dominant position and abuse it. Even if the possibility of a counter-attack is acceptable that attack must still be proportionate to the threat taking into account the economic strength of the undertakings confronting each other."³⁰¹

It is inherent in any limitation or refusal to supply with the result of a restriction of parallel distribution that the purpose is to strengthen the dominant position in the import country. On the other hand and as explained above the threat of parallel distribution against the profitability of the pharmaceutical undertakings is minimal, in particular because the pharmaceutical undertakings still profit from the sales in the export country and are in general a very profitable industry (see **Annex V**).

(e) *Conclusion*

None of the arguments presented so far by the pharmaceutical industry are sufficient to justify a refusal or limitation to supply of their products. Nor can they hide behind national regulatory systems. Finally, they lack any conclusive proof that parallel distribution of their products has more than marginal effects on their profitability or could in any way be harmful to consumers.

3.8 *Conclusion*

A limitation or refusal to supply by a dominant pharmaceutical undertaking that is intended to prevent parallel distribution of the products aims primarily to prevent intra-brand competition and leads to both a limitation of competition on the wholesaler level and to a foreclosure of national markets for the distribution of pharmaceuticals. It is therefore abusive in the sense of Article 82 EC.

²⁹⁹ Decision of the Greek Competition Commission 193/III/2001 of 3 August 2001, Glaxo Wellcome, GRURInt 2002, 534.

³⁰⁰ EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers? 2004, p. 50.

³⁰¹ Case 27/76, *United Brands v Commission* (1978) ECR 207, para. 184/194.

The protection of intra-brand competition and the protection of the single market from division into national markets is one of the main tasks of EU competition law and in particular of Article 82 EC.

Any intentional foreclosure of national markets by a dominant firm therefore has to be held as abusive *per se* under Article 82 EC since it is contrary to the basic concept of the EU single market. There is no objective justification for such behaviour.

National regulation of pharmaceutical prices and reimbursement cannot allow the pharmaceutical industry to engage in anti-competitive behaviour. Even in such areas of state intervention, dominant undertakings are obliged to compete on the merits only. Any easing of this fundamental concept by sector exceptions (e.g. for pharmaceuticals) would lead to unacceptable legal uncertainty.

Further grounds presented by the pharmaceutical industry to potentially justify a refusal to supply or supply limitation, for which the industry also has the burden of proof, are not convincing and do not withstand careful analysis. The opinion of Advocate General Jacobs in *Syfait* has shown that the arguments need to be scrutinised carefully against the factual background and that there is a high risk of drawing incorrect conclusions. In order to outweigh a restriction of intra-brand competition on the single market a justification must go beyond the protection of the undertaking's profits.

IV CONCLUSION

This report has shown that the initiatives of the pharmaceutical industry that aim to prevent, or have the effect of preventing, the parallel distribution of pharmaceuticals in Europe need effective policing by the relevant competition authorities and courts, at national and European level.

The assessment has shown that refusals to supply and supply limitations that hinder parallel distribution are clearly anti-competitive because they are directed against the achievements of the single European market.

Any serious and thorough analysis of supply restrictions needs to encompass a detailed examination of all the factors which determine the distribution of pharmaceuticals in Europe. In particular the definition of the market should reflect the specific circumstances faced by pharmaceutical distributors. The market for the distribution of branded prescription pharmaceutical products is fragmented according to individual products, leading to dominance of the pharmaceutical producers on each individual product market.

When restricting supplies with the aim of stymieing parallel distribution, pharmaceutical undertakings abuse their dominant position vis-à-vis wholesalers and foreclose national markets. As a result, the end consumer and national health systems are deprived of the benefits of the single European market and of the financial advantages that parallel distribution of pharmaceuticals can provide.

Annex I – Price Regulation

Country	System of price regulation	Criteria
Austria ³⁰²	<ul style="list-style-type: none"> ▪ price fixed by public authority if free market prices are too high ▪ voluntary price proposal by industry and approval of the authority <p>In theory it's a free pricing system. However, if the price commission at the Ministry for Social Affairs and Consumer Protection considers free market prices too high it may set maximum prices. Further, limitations on reimbursed price have an effect on the price setting.</p>	
Belgium ³⁰³	<ul style="list-style-type: none"> ▪ price proposal and approval of the authority ▪ price negotiations <p>Prices are suggested by the industry. If the Ministry of Economic Affairs does not reach a decision within 90 days the producer can directly apply the price requested.</p>	<ul style="list-style-type: none"> - therapeutic value, - cross-country comparison, - general and administrative costs and taxes; and - investment in R&D and salary costs.
Denmark	<ul style="list-style-type: none"> ▪ free pricing. <p>Before 1. April 2005 the Danish Association of the Pharmaceutical Industry (LIF) had guaranteed that the pharmacy purchase price would not exceed an average European price (AEP).</p>	
France	<ul style="list-style-type: none"> ▪ free pricing ▪ price negotiations <p>Prices can be set freely for any product except where it is included in the positive list of reimbursed pharmaceuticals.³⁰⁴</p> <p>The price is then fixed by a public authority within a scheme negotiated by the industry with CEPS (Comité économique des produits de santé)³⁰⁵.</p>	

³⁰² Preisgesetz 1992, BGBl. Nr. 145 (as amended).

³⁰³ Arrêté ministériel of 29.12.1989 relatif aux prix des médicaments non-remboursables, *M.B.*, 06.01.1990; Arrêté ministériel of 29.12.1989 relatif aux prix des médicaments remboursables, *M.B.*, 06.01.1990.

³⁰⁴ Article L 5123-1 Code de la Santé publique.

³⁰⁵ Article L 162-16-4 Code de la Sécurité sociale.

Country	System of price regulation	Criteria
Germany ³⁰⁶	<ul style="list-style-type: none"> ▪ free pricing <p>Wholesalers and pharmacists are obliged to comply with the German regulation on pharmaceutical prices, fixing (maximum) profit margins calculated on the basis of manufacturers sales price.</p>	<ul style="list-style-type: none"> - reference pricing
Greece ³⁰⁷	<ul style="list-style-type: none"> ▪ price fixing <p>Prices fixed by the Minister of Development in collaboration with the Minister of Health.</p> <p>A Pricing Committee is responsible to give non-binding expert opinions on the price level, taking into account price differentiations in other European countries that occurred after the initial price fixing.</p> <p>A special pricing system applies for pharmaceuticals consumed in hospital. Prices are reduced by 13% compared to the wholesale price.</p>	<ul style="list-style-type: none"> - production and distribution costs, - average ex-factory price in the three (3) European countries with the lowest prices (2 from the 15 "old" member states and 1 from the "new" ones) - The industry has the right to claim a higher price than the one resulting from the 3 countries by providing higher production costs.
Italy ³⁰⁸	<ul style="list-style-type: none"> ▪ price proposal and approval of the authority ▪ price negotiations <p>The price is negotiated between the applicant company and the Price and Reimbursement Committee (Agenzia Italiana del farmaco).</p>	<ul style="list-style-type: none"> - health economic data, - therapeutic value, - cross-country comparison - cost/ benefit data, - national turnover and investment in R%D, - pharmaceutical-economic studies (if available).
Netherlands ³⁰⁹	<ul style="list-style-type: none"> ▪ free pricing <p>In general, it is a free pricing system. The Drug Pricing Act sets however the maximum pharmacy purchase price for all reimbursed products.</p>	<ul style="list-style-type: none"> - cross-country comparison

³⁰⁶ Arzneimittelpreisverordnung vom 14. November 1980 (BGBl. I S. 2147) zuletzt geändert durch das Gesetzes vom 14. November 2003, Artikel 24 (BGBl. I S. 2190, 2254).

³⁰⁷ A different system was applied until June 2004 which has been declared unconstitutional by the Greek Supreme Court in May 2004. There is a proposal from 20 April 2005 for a new legislation. See e.g. PPR (2005), p.160.

³⁰⁸ CIPE (Interministerial Committee for the Economic Planning) resolution dated 1 February 2001.

³⁰⁹ Wet geneesmiddelenprijzen, wet van 25 januari 1996.

Country	System of price regulation	Criteria
Poland ³¹⁰	<ul style="list-style-type: none"> ▪ price proposal and approval of the authority ▪ price negotiations <p>The Medicines Management Team (Zespół do spraw Gospodarki Lekami) prepares an opinion for the individual case on the basis of company information and suggests a price. The Ministry of Health in co-operation with the Minister of Finance sets the retail and wholesale margins.</p>	<ul style="list-style-type: none"> - cross-country comparison, - reference prices, - cost / benefit data, - costs of production, - therapeutic value, - reimbursement costs.
Portugal ³¹¹	<ul style="list-style-type: none"> ▪ price proposal and approval of the authority ▪ price negotiations <p>The industry suggests a price to the Direcção Geral do Comércio e da Concorrência that is based on a cross-country comparison. If it is not notified otherwise within 60 days, the price is approved.</p>	<ul style="list-style-type: none"> - cross-country comparison, alternatively reference prices.
Spain ³¹²	<ul style="list-style-type: none"> ▪ price proposal and approval of the authority ▪ price negotiations <p>Prices are determined on the basis of an economic report that sets out the real costs for the development of the product.</p>	<ul style="list-style-type: none"> - development costs, - company status, - sales estimations, - production costs.
Sweden ³¹³	<ul style="list-style-type: none"> ▪ free pricing <p>However, there are limitation to the reimbursement price which indirectly influence the price setting.</p>	

³¹⁰ USTAWA z dnia 5 lipca 2001 r. o cenach., Dz.U. Nr 97 poz. 1050, z 2001, Art. 5, Art. 6, Art. 7; ROZPORZĄDZENIE MINISTRA ZDROWIA z dnia 20 grudnia 2004 r.w sprawie ustalenia cen urzędowych hurtowych i detalicznych na produkty lecznicze i wyroby medyczne, Dz.U. Nr 275 poz. 2733, z 2004.

³¹¹ Portaria n.º 577/2001, 7 June; Portaria n.º 914/2003, 1 September; Portaria n.º 29/90, 13 January; Portaria n.º 338/90, 3 May; Decreto-Lei n.º 206/2000, 1 September.

³¹² Ley 25/1990 de 25 de noviembre, del Medicamento (BOE de 22 de diciembre 1990, núm. 306, pág. 38228), Articles 100 to 104; Real Decreto 271/1990, de 23 de febrero sobre reorganización de la intervención de precios de especialidades farmacéuticas de uso humano (BOE de 2 de marzo de 1990, núm. 53, pág. 6086); Ley 16/2003, de 28 de mayo de cohesión y calidad del Sistema Nacional de Salud (BOE de 29 de mayo de 2003, núm. 23, pág. 20567), Disposición final tercera; Ley 55/1999 de 29 de diciembre sobre medidas fiscales, administrativas y del orden social (BOE de 30 de diciembre de 1999, núm. 312, pág. 46095), Artículo 77.

³¹³ SFS 2002:160. Lag (2002:160) om läkemedelsförmåner m.m. § 7 och § 13; LFNFS 2003:01; Läkemedelsförmånsnämndens föreskrifter (LFNFS 2003:1) om ansökan och beslut hos Läkemedelsförmånsnämnden enligt lagen (2002:160) om läkemedelsförmåner m.m. § 6 och § 8.

Country	System of price regulation	Criteria
UK ³¹⁴	<ul style="list-style-type: none"> ▪ free pricing for new active substance products <p>Though, in certain cases dependent on the anticipated profit of a new product, notification obligations might exist.</p> <p>If a new product does not receive a new active substance marketing authorisation, the company must seek the Department of Health's agreement to the price.</p>	<p>Criteria for the approval of a new product, which did not receive a new substance marketing authorisation:</p> <ul style="list-style-type: none"> - reference prices, - forecast sales, - therapeutic value, - any exceptional costs.

³¹⁴ Pharmaceutical Price Regulation Scheme (PPRS) an agreement for the purposes of section 33 of the Health Act 1999.

Country	System of reimbursement regulation	Criteria								
Denmark ³¹⁶	<ul style="list-style-type: none"> ▪ positive list ▪ co-payment ▪ individual reimbursement upon request <p>Reimbursement is based on the individual need, and the rate of a given patient's prior consumption within the individual reimbursement period of one year. There are however special provisions for children and persons with a large need.</p> <p>Reimbursement will be granted to persons above 18 years according to the costs of the product:</p> <table style="margin-left: 20px; border: none;"> <tr> <td>DKK 0- 500</td> <td style="text-align: right;">0%</td> </tr> <tr> <td>DKK 500-1200</td> <td style="text-align: right;">50%</td> </tr> <tr> <td>DKK 1200- 2800</td> <td style="text-align: right;">75%</td> </tr> <tr> <td>Over DKK 2800</td> <td style="text-align: right;">85%</td> </tr> </table> <p>The reimbursement scheme runs for one year, after which the allowances are reset to zero.</p>	DKK 0- 500	0%	DKK 500-1200	50%	DKK 1200- 2800	75%	Over DKK 2800	85%	<ul style="list-style-type: none"> - therapeutic value - reference price - prescription only
DKK 0- 500	0%									
DKK 500-1200	50%									
DKK 1200- 2800	75%									
Over DKK 2800	85%									
France ³¹⁷	<ul style="list-style-type: none"> ▪ positive list ▪ co-payment <p>Reimbursement is based on the classification of the pharmaceutical :</p> <p>100% for drugs which are irreplaceable and which price is very high;</p> <p>35% for all drugs for minor diseases</p> <p>65% for all the others</p>									
Germany	<ul style="list-style-type: none"> ▪ negative list with active ingredients ▪ co-payment <p>Reimbursement only for prescribed drugs, exceptions for children up to 12 years, adolescent up to 18 years in case of disorders and treatment of severe diseases.</p> <p>Co-payment between 5 and 10 EUR, exemptions possible.</p>									
Greece ³¹⁸	<ul style="list-style-type: none"> ▪ positive list ▪ co-payment <p>Uniform co-payment of 25%.</p> <p>Exemptions for certain medicines and population groups that are not subject to co-payment or a reduced co-payment of 10%.</p>	<ul style="list-style-type: none"> - classification in the ATC system - daily treatment dose - daily treatment costs - therapeutic efficiency - reference price 								

³¹⁶ Bekendtgørelse af lov om offentlig sygesikring, LBK nr. 509 af 01/07/1998.

³¹⁷ Articles L 162-16-4 et L 322-1 du Code de la Sécurité sociale.

Country	System of reimbursement regulation	Criteria										
Spain ³²²	<ul style="list-style-type: none"> ▪ positive list ▪ co-payment <p>Reimbursement is limited to the reference price set by the government.</p> <p>There is a 40% co-payment. However, no co-payment has to be done by pensioners and in case of work accidents and for other social reasons.</p>	<ul style="list-style-type: none"> - social importance of the group of medicines that the product belongs to. - therapeutic value - expected duration of the treatment and frequency of administration,. - existence of available alternatives with lower price or treatment costs. 										
Sweden ³²³	<ul style="list-style-type: none"> ▪ positive list ▪ co-payment <p>Upon application the Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden LFN), an independent governmental agency, decides and includes the selected products in the national reimbursement policy with a specific price.</p> <p>Reimbursement is based on the price of the pharmaceutical:</p> <table style="margin-left: 40px;"> <tr> <td>€ 0-100</td> <td>100%</td> </tr> <tr> <td>€ 100-170</td> <td>90%</td> </tr> <tr> <td>€ 170-330</td> <td>75%</td> </tr> <tr> <td>€ 330-430</td> <td>50%</td> </tr> <tr> <td>Over € 430</td> <td>0%</td> </tr> </table> <p>Within a 12 month period the co-payment is limited to € 200. Any additional prescribed medical products are free of charge for the patient.</p>	€ 0-100	100%	€ 100-170	90%	€ 170-330	75%	€ 330-430	50%	Over € 430	0%	<ul style="list-style-type: none"> - cost-effectiveness - only on prescription - therapeutic value - general health economy
€ 0-100	100%											
€ 100-170	90%											
€ 170-330	75%											
€ 330-430	50%											
Over € 430	0%											
UK ³²⁴	<ul style="list-style-type: none"> ▪ positive list <p>The Drug Tariff is produced on a monthly basis by the Prescription Pricing Authority</p> <p>Full reimbursement is given unless the products are subsequently blacklisted or have to be prescribed only under certain circumstances.</p>	<ul style="list-style-type: none"> - therapeutic value - cost effectiveness 										

³²² Ley 25/1990 de 25 de noviembre, del Medicamento (BOE de 22 de diciembre 1990, núm. 306, pág. 38228), Artículo 94; Real Decreto 83/1993, de 22 de enero que regula la selección de los medicamentos a efectos de su financiación por el Sistema Nacional de Salud (BOE de 19 de febrero de 1993, núm. 43, pág. 5292); Real Decreto 1035/1999, de 18 de junio sobre el sistema de precios de referencia en la financiación con cargo a fondos de la Seguridad Social o a fondos estatales afectos a la sanidad (BOE de 29 de junio de 1999, núm. 154, pág. 24521); Ley 16/2003, de 28 de mayo de cohesión y calidad del Sistema Nacional de Salud (BOE de 29 de mayo de 2003, núm. 23, pág. 20567), Disposición final tercera.

³²³ SFS 2002:160. Lag (2002:160) om läkemedelsförmåner m.m. § 5 och § 17.

³²⁴ Drug Tariffs by the Department of Health, published monthly.

Annex III – Substitution Policy

Country	Doctor level	Pharmacist level		Wholesaler level
		In case of branded product prescription	In case of active ingredient prescription	
Austria ³²⁵	Obligation to prescribe branded products and not active ingredients. Recommendation to prescribe cheapest therapeutic substitute.	No substitution possible.	Not applicable.	No substitution possible.
Belgium ³²⁶	No obligation to prescribe a brand or an active ingredient. Doctors are encouraged to prescribe cheaper generics or parallel traded products.	No substitution possible. ³²⁷	No substitution possible.	No substitution possible.

³²⁵ Bundesgesetz vom 25. Oktober 1972 über die Abgabe von Arzneimitteln auf Grund ärztlicher Verschreibung (Rezeptpflichtgesetz), BGBl. Nr. 413/1972 (as amended); Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen of 8.1.2005.

³²⁶ Arrêté Royal du 19.03.04 réglementant le traitement de substitution, *M.B.*, 30.04.04; Art. 11 of the Arrêté Royal N°78 of 10. 11.1967 relatif à l'exercice des professions des soins de santé (*M.B.* 14.11.1967; Art. 22bis de l'arrêté royal du 06.06.1960, *M.B.*, 22.06.1960.

³²⁷ Art. 11 of the Arrêté Royal N° 78 of 10.11.1967 allows substitution by pharmacists but the enforcement is subject to a further Royal Decree which is not yet adopted.

Country	Doctor level	Pharmacist level		Wholesaler level
		In case of branded product prescription	In case of active ingredient prescription	
Denmark	<p>No obligation to prescribe branded products or active ingredients.</p> <p>Recommendation to prescribe cheapest therapeutic substitute.</p> <p>Doctors can add "no substitution" if there is a strong reason.</p>	<p>Obligatory substitution, unless price difference is within defined modest thresholds.</p> <p>No differentiation between generics and parallel trade.</p>	Not applicable.	No substitution possible.
France	<p>No Obligation to prescribe a brand or an active ingredient.</p> <p>Doctors are encouraged to prescribe cheaper generics or parallel traded products³²⁸.</p>	<p>May substitute with a cheaper product for the same indications if doctor does not indicate "not to be substituted".³²⁹</p>	Not applicable.	No substitution possible.

³²⁸ Article L 162-1 du Code de la Sécurité Sociale.

³²⁹ Article R 5015-61 du Code de la Santé Publique.

Country	Doctor level	Pharmacist level		Wholesaler level
		In case of branded product prescription	In case of active ingredient prescription	
Germany	<p>No obligation to prescribe a brand product or an active ingredient.</p> <p>However, doctors are not allowed to exceed cap on expenditure value, which is an incentive to prescribe a cheaper product.</p> <p>Further, doctors have to take into consideration their duty of economic efficiency.</p>	<p>Must substitute with a cheaper product if the doctor did not indicate "no substitution" (so called aut-idem).</p> <p>Must take import products up to the importation quote (in principal 5 %) if imported products that are 15 % cheaper than the original product or at least 15 EUR cheaper are subject to the substitution rule.</p> <p>By dispensing imported medicines the pharmacy has to reach a commercial reserve of 10 % of the turn over fixed by the import quota.</p>	<p>Must hand out a cheaper product which could be either a generic or a parallel imported product.</p> <p>Must take import products up to the importation quote (in principal 5 %) if imported products are 15 % cheaper than the original product or at least 15 EUR cheaper are subject to the substitution rule.</p> <p>By dispensing imported medicines the pharmacy has to reach a commercial reserve of 10 % of the turn over fixed by the import quota.</p>	No substitution possible.
Greece	Obligation to prescribe branded products, not active ingredients.	No substitution possible.	Not applicable.	No substitution possible.
Italy ³³⁰	<p>No obligation to prescribe an active ingredient.</p> <p>However, doctors are not allowed to exceed cap on expenditure value, which is an incentive to prescribe the cheapest product.</p>	May substitute with generic if doctor does not indicate "not to be substituted".	The pharmacist may alternatively also sell the generic or parallel traded product.	No substitution possible.

³³⁰

Decree on pharmaceutical traceability dated July 15th 2004.

Country	Doctor level	Pharmacist level		Wholesaler level
		In case of branded product prescription	In case of active ingredient prescription	
Netherlands	<p>No obligation to prescribe a brand or an active ingredient.</p> <p>The doctors are encouraged by campaigns to prescribe generic names and not use brand names.</p>	<p>Substitution with generic or with a cheaper product possible.</p> <p>Financial incentive: one third of the difference between the price of the dispensed medicinal product and the price of the highest equal medicinal product can be charged to the patient or his insurance company.</p>	<p>Substitution with generic or with a cheaper product possible.</p> <p>Financial incentive: one third of the difference between the price of the dispensed medicinal product and the price of the highest equal medicinal product can be charged to the patient or his insurance company.</p>	No substitution possible.
Poland ³³¹	<p>No obligation to prescribe a brand or an active ingredient.</p> <p>Doctors can add "no substitution" when prescribing a brand name.</p>	<p>Obligation to inform the patient about a cheaper substitute with identical substance, strength and form, if permitted by the doctor.</p>	<p>Obligation to inform the patient about a cheaper substitute with identical substance, strength and form, if permitted by the doctor.</p>	No substitution possible.
Portugal	<p>No obligation to prescribe a brand or an active ingredient.</p> <p>Doctors must prescribe by the active ingredient whenever exists a generic.</p>	<p>May substitute with a generic, when permitted by the doctor.</p> <p>Obligation to inform the patient of the cheapest generic. This can only be rejected expressly (by signature) by the patient.</p> <p>Parallel imported products are not existent.</p>	<p>May substitute with a generic, when permitted by the doctor.</p> <p>Parallel imported products are not existent.</p>	No substitution possible.

³³¹ USTAWA z dnia 23 stycznia 2003 r. o powszechnym ubezpieczeniu w Narodowym Funduszu Zdrowia, Art. 60, Ust.5, Dz.U. Nr 45, poz. 391, z 2003.

Country	Doctor level	Pharmacist level		Wholesaler level
		In case of branded product prescription	In case of active ingredient prescription	
Spain ³³²	No obligation to prescribe a brand or an active ingredient.	Substitution with generic or parallel imported product only if the product is not at hand. In some regions obligation to substitute with generic at lower price when the active ingredient is prescribed and the generic product price is equal or below the retail price.		No substitution possible.
Sweden	Obligation to prescribe branded products.	Obligation to choose the cheapest alternative. Doctor is allowed to reject substitution to a generic by signature; and is allowed to reject substitution to a parallel import by signature and product company name.		No substitution possible.
UK	No obligation to prescribe a brand product or an active ingredient. Doctors are encouraged to prescribe cheaper products.	Substitution only with a parallel import.	May substitute with generic, or if not available with parallel import. No obligation, only subject to economic considerations.	No substitution possible.

³³²

Art. 90, 94 Ley 25/1990 de 25 de noviembre, del Medicamento (BOE de 22 de diciembre 1990, núm. 306, pág. 38228).

Annex IV – State contribution to R&D

Who contributed Most to Development of Top Five Selling Drugs (1995)						
Importance of research	Affiliation of Scientist	Ranitidine (Zantac) GSK	Acyclovir (Zovirax) GSK	Captopril (Capoten) Bristol-Meyers Squibb and Enalapril (Vasotec) MSD	Fluoxetine (Prozac) Eli Lilly	Total
Key contributions to discovery and Development of Drug*	U.S. taxpayer studies	2	4	4	1	11
	Foreign academic studies	1	1	1	2	5
	Industry sponsored studies (excluding patent holder)	0	0	0	0	0
	Patent-holder sponsored studies	0	0	0	1	1
Referenced in Patent Holders' papers*	U.S. taxpayer studies	0	7	1	1	9
	Foreign academic studies	0	1	0	1	2
	Industry sponsored studies (excluding patent holder)	0	0	0	0	0
	Patent-holder sponsored studies	0	0	0	0	0
Other Contributions to Discovery and Development of Drug	U.S. taxpayer studies	6	21	9	16	52
	Foreign academic studies	15	8	4	6	33
	Industry sponsored studies (excluding patent holder)	4	0	0	3	7
	Patent-holder sponsored studies	2	2	3	4	11
Total		30	44	22	35	131
Percent of total research projects sponsored by U.S. taxpayer or foreign academic institutions		80%	95%	86%	77%	85%

*As defined by the NIH. (Source: National Institutes of Health, "NIH Contributions to Pharmaceutical Development" Administrative Document, February 2000.)

Annex V – Annual profit and annual expenses for R&D

	2001	2002	2003	2004
AstraZenca	4,156	4,356	4,111	4,770
GlaxoSmithKline	8,551 (4.697£)	10,308 (5.662 £)	11,850 (6.509 £)	11,196 (6.150 £)
MSD (net income)	7,282	7,149	6,831	5,813
Novartis	4,325	5,092	5,889	6,539
Pfizer (net income)	7,788	9,126	3,910	11,361
Roche Group	2,627 (3.247 CHF)	1,080 (1.335 CHF)	4,525 (5.592 CHF)	7,727 (8.979CHF)

Annual Profit in million \$ (source: annual reports of the pharmaceutical companies)

	2001	2002	2003	2004
Astra Zeneca	2,773	3,069	3,451	3,803
GlaxoSmithKline	4,869	5,206	5,279	5,410
MSD	2,456	2,677	3,280	4,010
Novartis	2,528	2,843	3,756	4,207
Pfizer	4,982	5,208	7,487	7,684
Roche				
only pharma			3,267	3,649
total R &D	3,262	3,567	3,993	4,267

Annual expenses for R&D in million \$ (source: annual reports of the pharmaceutical companies)

2003	Sales	Profits	Marketing expenses	R&D expenses
AstraZeneca	18,849	4,111	6,856	3,451
GSK	35,163	11,850	12,403	5,279
MSD	22,485	6,831	6,394	3,280
Novartis	24,864	5,889	7,854	3,756
Pfizer	45,200	3,910	15,242*)	7,684
Roche	22,650	4,525	6,553	3,649

Comparison for the year 2003 in mill \$ (source: annual reports of the pharmaceutical companies)

*) Pfizer: Selling, informational and administrative expenses.

Annex VI – Pharmaceutical promotional expenditure in Europe, 2003

Country	spend (€ million)	% increase over 2002
Germany	1,914.93	24.6
Italy	1,041.71	20.3
France	890.57	12.7
Spain	515.78	26.1
UK	316.81	15.3

(Source: IMS Health)

Annex VII – National public service obligations

Country	Wholesaler	Pharmacist
Austria ³³³	No obligation to hold stock.	Obligation to hold necessary stock, in particular of listed products, to meet the demand and deliver as soon as possible.
Belgium ³³⁴	<p>Obligation to hold stock of :</p> <ul style="list-style-type: none"> ▪ 2/3 of all market products ▪ at least equivalent of last year's monthly turnover <p>Obligation to ensure emergency delivery and a replacement wholesaler can ensure delivery.</p>	No obligation to hold stock.
Denmark ³³⁵	<p>No obligation to hold stock.</p> <p>Due to competition wholesalers tend to be full line wholesalers.</p>	Obligation to hold sufficient stock to meet demand and to deliver as soon as possible.
France ³³⁶	<p>Obligation to hold sufficient stock to meet demand and to deliver as soon as possible.</p> <p>Obligation to inform Public authority as soon as there is a reduction of stock.</p>	No obligation to hold stock.
Germany		<p>Depending on the pharmaceutical</p> <ul style="list-style-type: none"> ▪ obligation to hold a constant stock; ▪ obligation to hold stock of at least for the average need of one week; ▪ obligation to make sure that it can be supplied immediately.
Greece	Obligation to hold stock of last years sales plus 20%.	No obligation to hold stock.

³³³ Apothekenbetriebsordnung 2005, BGBL II Nr. 65/2005.

³³⁴ Art. 22bis de l'arrêté royal du 06.06.1960, *M.B.*, 22.06.1960.

³³⁵ Bekendtgørelse af lov om apoteksvirksomhed (Apotekerloven) - LBK nr 657 af 28/07/1995, clause 41.

³³⁶ Article L5124-6 du Code de la Santé Publique.

Italy ³³⁷	<p>Obligation to hold stock of:</p> <ul style="list-style-type: none"> ▪ listed products to ensure usual and emergency pharmaceutical service. ▪ 90% of all the pharmaceutical products in commerce. ▪ at least one pre-packed product industrially prepared per each of the formulations contained in National Official Pharmacopeia actually in commerce. <p>Obligation to comply with the guidelines on good distribution practice.</p>	<p>Obligation to hold stock of:</p> <ul style="list-style-type: none"> ▪ listed products to ensure usual and emergency pharmaceutical service.
Netherlands	No obligation to hold stock.	
Poland ³³⁸	No obligation to hold stock.	Obligation to hold sufficient stock to meet demand and to deliver as soon as possible.
Portugal ³³⁹	Obligation to hold sufficient stock to meet demand in emergency situation and to deliver as soon as possible.	Obligation to deliver as soon as possible if out of stock.
Spain ³⁴⁰	<p>Obligation to hold stock of:</p> <ul style="list-style-type: none"> ▪ listed products to ensure usual and emergency pharmaceutical service; ▪ variety of products to meet constant demand. 	No obligation to hold stock.
Sweden ³⁴¹	No obligation to hold stock.	Obligation to offer all products in the reimbursement system.
UK ³⁴²	No obligation to hold stock.	Obligation to deliver as soon as possible.

³³⁷ Law Decree no. 538 dated December 30th, 1992; Decree no. 1706 dated 30/09/1938.

³³⁸ USTAWA z dnia 6 września 2001 r. Prawo farmaceutyczne, Dz.U. Nr 53 poz. 533 z 2004, Art.95, Ust. 1,2,3.

³³⁹ Decreto-Lei 348/98, 15th June-clause 9.3, Decreto-Lei 48547, 27th August.

³⁴⁰ Real Decreto 2259/1994, de 25 de noviembre, por el que se regula los almacenes farmacéuticos y la distribución al por mayor de medicamentos de uso humano y productos farmacéuticos.

³⁴¹ Law (1996:1152) om handel med läkemedel m.m.

³⁴² Drug Tariffs by the Department of Health, published monthly.