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***Role of Competition in the Pharmaceutical Sector
and its Benefits for Consumers***

Contribution

By

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The views expressed are those of the author and do not necessarily reflect the views of
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In this paper the European Commission provides an overview of different aspects of its competition policy and enforcement activities in the pharmaceutical sector and its benefits for consumers.

The Pharmaceutical Sector Inquiry of 2008 is a good point to start this overview. In her speech of 16 January 2008¹ on the opening of the sector inquiry the European Commissioner for Competition at the time, Ms Kroes, highlighted in particular the beneficial effects which competition has on consumers and the need for competition authorities to be vigilant that anti-competitive practices do not take away such benefits in a sector which is of special importance to them:

"I chose the pharmaceuticals sector to be the focus of the Commission's next sector inquiry because in my term as Competition Commissioner I have focused on solving competition problems that make a difference to the lives of individuals. Few things make more of a difference than this.

The pharmaceuticals sector is vital to the health of Europe's citizens. As well as being a vital sector of the economy, medicines are a major expense. Medicines cost us all a lot of money—we spend around 200 billion euros each year on pharmaceuticals; that's around 400 euros for every man, woman and child in the 27 Member States of the European Union."

This focus on the pharmaceutical sector and its impact on consumers has remained at the centre attention of the European Commission's competition policy initiatives and follow-up activities since.

In the following sections of this paper we will illustrate this point by discussing the Commission's recent enforcement of EU antitrust rules in the pharmaceutical sector, followed by an overview of the issues which play in the distribution of pharmaceuticals.

¹ [http://europa.eu/rapid/press-release SPEECH-08-18_en.htm?locale=en](http://europa.eu/rapid/press-release_SPEECH-08-18_en.htm?locale=en)

I. Recent enforcement of EU antitrust rules in the pharmaceutical sector

1. Introduction

The Commission has in recent years investigated practices by pharmaceutical companies that may have undermined effective competition in the pharmaceutical markets, in particular practices to delay or hamper the introduction of generic medicines upon patent expiry.

Thanks to generic competition, patients can have access to affordable healthcare: through generics they can get their treatment significantly cheaper. It also ensures that public health systems can remain economically sustainable in times of budgetary constraints. Pharmaceutical expenditure absorbs significant portions of budgets of governments and households. It is therefore crucial that European citizens are not deprived of cheaper health bills by anticompetitive practices. Moreover, competition by generics is also a dynamic force which stimulates pharmaceutical companies to continue to invest in research and to develop innovative treatments, as they cannot rely forever on their current blockbuster products.

In 2008, the Commission launched the Pharmaceutical Sector Inquiry (SI) aimed at uncovering the causes of the apparent low levels of competition in this sector. The SI final report, published in July 2009, showed a decline in the number of novel medicines reaching the market and identified significant delays in the market entry of generic drugs. SI findings suggested that company practices are among the causes, but do not exclude other factors such as shortcomings in the regulatory framework.²

The use of specific practices by originator and generic companies in order to delay generic entry has since been subject to increased scrutiny by competition authorities if used in a way that may constitute an infringement under Article 101 or 102 of the TFEU. These potentially anti-competitive practices notably include the misuse of the patent and regulatory systems and the so-called pay-for-delay agreements (often in the context of patent settlements).

A number of antitrust investigations have been conducted, some of which are still under way. The Commission has adopted decisions in the Citalopram case³ the Fentanyl case⁴ and the Perindopril case⁵.

² The full texts of the Commission Communication on the final report (hereinafter: Commission Communication) as well as the final report as technical annex to the communication are available at the website of DG Competition: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>. See also Press Release IP/09/1098 and MEMO/09/321.

³ http://europa.eu/rapid/press-release_IP-13-563_en.htm.

The Commission has also been monitoring patent settlements between pharmaceutical companies, focusing its attention on those that might limit or delay the market entry of generic drugs. As a result of this exercise, the Commission has published since 2010 yearly reports on the monitoring of patent settlements, providing figures on the evolution of the number and types of patent settlement agreements signed by pharmaceutical companies in Europe.

Regarding the misuse of the patent and regulatory systems, in December 2012 the Court of Justice of the EU dismissed an appeal brought by AstraZeneca against the judgement by the General Court of 2010, which had largely upheld the Commission's decision of 2005.⁶ The Court's judgement made it clear that misuse of regulatory procedures, including the patent system, may infringe EU competition rules.

This section aims at providing an overview of these recent developments on the Commission's efforts to enforce EU competition law in European pharmaceutical markets.

2. The AstraZeneca case

On 15 June 2005 the Commission adopted a decision on inter-brand competition by which it found that AstraZeneca had committed two abuses of a dominant position. AstraZeneca was fined for abusing its dominant position by misusing the rules for the grant of supplementary patent certificates and marketing authorisations to delay generic entry of its ulcer treatment drug Losec.

The first abuse consisted mainly of a pattern of allegedly misleading representations made before the patent offices in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom. The second abuse consisted of the submission of requests for deregistration of the marketing authorisations for Losec capsules in Denmark, Norway and Sweden, combined with the withdrawal from the market of Losec capsules and the launch of a new version of that product (Losec MUPS tablets) in those three countries. The abuses found constituted abuses of regulatory proceedings.

This was the first Commission's decision on abuse of dominance in the pharmaceutical

⁴ http://europa.eu/rapid/press-release_IP-13-1233_en.htm

⁵ http://europa.eu/rapid/press-release_SPEECH-14-541_en.htm

⁶ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770

markets. It fined AstraZeneca €60 million due to its infringements of Article 102 TFEU and Article 54 of the European Economic Area (EEA) Agreement (IP/05/737).

AstraZeneca appealed the Commission's decision, but in July 2010 the General Court⁷ very largely dismissed the appeal by AstraZeneca, upholding the Commission's decision. With this judgement, the General Court confirmed that Article 102 of the TFEU, which prohibits abuses by dominant companies, applies to the pharmaceutical sector. The General Court annulled part of the Commission's decision in respect of the second abuse, insofar as it concerned the restrictions on parallel trade in two of the three countries concerned, resulting in a lowering of the fine from 60 to 52.5 million euros.

In relation to the first abuse, the General Court confirmed that AstraZeneca's conduct amounted to "a consistent and linear course of conduct, characterised by the communication to the patent offices of misleading representations for the purpose of obtaining the issue of SPCs (Supplementary Protection Certificates) to which it was not entitled or to which it was entitled for a shorter period".⁸ Through its conduct, AstraZeneca obtained additional so-called SPC protection in several countries. Such intellectual property protection constituted a principal entry barrier for generic versions of an original medicine. The General Court rejected AstraZeneca's claims that its conduct constituted normal competition and that it could be explained by errors or unauthorised behaviour by AstraZeneca's patent agents. More generally, the General Court found that the assessment whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made in concreto and may vary according to the specific circumstances of each case.

As regards the second abuse, the General Court validated the Commission's conclusion that a key purpose underlying AstraZeneca's deregistration of market authorisations for Losec in selected EEA countries was to exclude competition from generic firms and parallel traders. The General Court ruled that the purpose of a market authorisation was to confer the right to market a pharmaceutical product and not to exclude competitors from the market. Moreover, the General Court stated that an undertaking which holds a dominant position has a special responsibility under Article 102 and that it cannot therefore use regulatory procedures in such a way as to prevent or make more difficult entry of competitors on the market, in the absence of grounds relating to the defence of legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.

⁷ Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266
⁸ Paragraph 598 of the judgement.

The General Court also found that the illegality of abusive conduct under Article 102 is unrelated to the compliance or non-compliance by an undertaking of other legal rules and that in the majority of cases abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.

AstraZeneca appealed the General Court's judgement, but in December 2012 the Court of Justice of the EU⁹ dismissed the appeal, in what became the first ruling by the Court of Justice on a Commission's decision on the abuse of a dominant market position in the pharmaceutical sector.

The Court of Justice's judgement clarified a number of issues of principle in relation to market definition, dominance and the concept of an abuse in the meaning of Article 102 TFEU. In particular, it confirmed that misuses of regulatory procedures could in certain circumstances constitute abuses of a dominant position within the meaning of EU antitrust rules (Article 102 of the TFEU). The judgment also confirmed the Commission's method to define the relevant product market and existence of a dominant position in that case. The judgment also confirmed that intellectual property rights constitute a factor relevant to the determination of dominance.

3. The legal and economic assessment of pay-for-delay agreements

In the pharmaceutical sector, once the SPC period has expired and the active ingredient is no longer protected, that active ingredient can in principle be used by generic companies to produce and sell generic medicines containing the identical active ingredient in question. In that situation, the originator and the generics involved in the development of the generic versions of the same product may be at least potential competitors, if not already actual ones. They should therefore, in principle, show independent commercial conduct.

Often potential generic entrants challenge the validity of the patents or protection enjoyed by originators, either seeking a declaration of invalidity by a court or entering the market at risk. Conversely, originators may claim that a potential generic competitor may be infringing some of its patents. In this context, originator and generic companies are generally entitled to reach an agreement and settle their patent litigation, avoiding the costs of pursuing litigation to

⁹ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770

judgement. Patent settlements can bring real benefits through avoided litigation costs and earlier generic entry.

The jurisprudence has established that agreements between companies regarding patents, including agreements dealing with or settling patent disputes, are not immune from competition law scrutiny.

The overwhelming majority of patent settlement agreements are in fact entirely legitimate. However, an agreement between an originator and its potential generic competitors to prevent generic entry in exchange for a value transfer from the originator can be a restriction of competition contrary to Article 101 of the TFEU. This is notably the case when the value transfer induces the delay in market entry by the generic potential entrant.

The Commission's efforts to enforce antitrust rules in the pharmaceutical sector has materialised in a number of investigations concerning pay-for-delay agreements. The Commission has adopted decisions in the Lundbeck (Citalopram) case¹⁰, the Fentanyl case¹¹ and the Servier (Perindopril) case¹².

3.1. The Lundbeck (Citalopram) case

In July 2013, the Commission adopted the decision of imposing a fine of €93.8 million on Lundbeck and fines totalling €52.2 million on several producers of generic medicines for delaying generic market entry of the drug Citalopram. According to the Commission's findings, the agreements between Lundbeck and its generic competitors concerning Citalopram – namely, Alpharma, Merck, Arrow and Ranbaxy - violated Article 101 of the TFEU that prohibits anticompetitive agreements. The Citalopram decision has been the first prohibition decision by the Commission concerning pay-for-delay patent settlement agreements.

Citalopram is a medicine developed by Danish pharmaceutical company Lundbeck to treat the symptoms of major depression. In 2002, this product, which was Lundbeck's best-selling medicine, was nearing the end of its life cycle. After Lundbeck's basic patent for the Citalopram molecule had expired, it only held a number of related process patents which provided a more limited protection. At that point, it therefore became possible for competitors

¹⁰ http://europa.eu/rapid/press-release_IP-13-563_en.htm

¹¹ http://europa.eu/rapid/press-release_IP-13-1233_en.htm

¹² http://europa.eu/rapid/press-release_IP-12-835_en.htm

to enter the market with generic versions of Citalopram. Indeed, one of them started to sell generic Citalopram while others were all preparing to launch their own versions of the product.

However, when these generic competitors were close to entering the market, Lundbeck agreed with each of them that they would stay out. Instead of competing, the generic producers agreed not to enter the market in return for substantial payments and other inducements from Lundbeck amounting to tens of millions of euros. Lundbeck paid significant lump sums, purchased generics' stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement. The agreements gave Lundbeck the certainty that the generics producers would stay out of the market for the duration of the agreements without giving the generic producers any guarantee of market entry thereafter. Lundbeck did not prevent market entry by successfully enforcing its patent rights; rather, it simply paid other companies so that they would not compete, giving them the equivalent of what they would have earned if they had entered the market. This means they shared the monopoly rents among themselves: internal documents even spoke of this group of companies as a "club" and referred to "a pile of dollars" to be shared.

All this occurred at the expense of patients who were deprived of access to cheaper medicines. It also harmed public health systems, which for a longer period had to artificially bear the costs of an expensive medicine – and one of the most widely prescribed antidepressants. The difference in price was not small: in the UK once generic versions of Citalopram did enter the market, prices dropped on average by 90%.

3.2. The Fentanyl case

After investigating an agreement between J&J and Novartis, in December 2013 the Commission concluded that it was an anticompetitive agreement with the object of delaying the market entry of a cheaper generic version of the painkiller Fentanyl in the Netherlands, infringing Article 101 of the TFEU. The Commission imposed fines of €10.7 million on J&J and €5.4 million on Novartis.

The Fentanyl case constitutes an example of a pay-for-delay agreement that is unrelated to any patent dispute or litigation. This type of agreement has been referred to as "naked" pay-for-delay agreement.

Fentanyl is a painkiller 100 times more potent than morphine. It is used notably for patients

suffering from cancer. US pharmaceutical company Johnson & Johnson (J&J) initially developed Fentanyl and commercialised it in different formats since the 1960s. In 2005, J&J's protection on the Fentanyl depot patch had expired in the Netherlands and the Dutch subsidiary of Swiss firm Novartis, Sandoz, was on the verge of launching its generic Fentanyl depot patch. It had already produced the necessary packaging material.

However, in July 2005, instead of actually starting to sell the generic version, Sandoz concluded a so-called "co-promotion agreement" with Janssen-Cilag, J&J's Dutch subsidiary. The agreement provided strong incentives for Sandoz not to enter the market. Indeed, the agreed monthly payments exceeded the profits that Sandoz expected to obtain from selling its generic product, for as long as there was no generic entry. Consequently, Sandoz did not offer its product on the market. The agreement was stopped in December 2006 when a third party was about to launch a generic Fentanyl patch.

The agreement therefore delayed the entry of a cheaper generic medicine for seventeen months and kept prices for Fentanyl in the Netherlands artificially high - to the detriment of patients and taxpayers who finance the Dutch health system.

According to internal documents there would be no entry into the Dutch market in exchange for "a part of [the] cake". Instead of competing, Janssen-Cilag and Sandoz agreed on cooperation so as "not to have a depot generic on the market and in that way to keep the high current price". Janssen-Cilag did not consider any other existing potential partners for the so-called "co-promotion agreement" but just focused on its close competitor Sandoz. Sandoz engaged in very limited or no actual co-promotion activities.

3.3. The Servier (Perindopri) I case

On 9 July 2014, the Commission adopted a Decision in the Perindopril case, which deals with two sets of practices, all in relation with the medicine perindopril, a cardiovascular medicine originally developed by the French pharmaceutical company Servier: (i) unilateral behaviour by Servier, and (ii) patent settlement agreements between that company and a number of generic competitors. This is the third pay-for-delay case investigated by the Commission, and the first one that applied Article 102 TFEU.

Under Article 101 TFEU, the Decision established that Servier concluded 5 settlement agreements (between 2005 and 2007) with potential competitors which had the object and effect of restricting competition and thus infringed Article 101 TFEU. Generic companies

agreed not to compete in exchange for significant inducements. These inducements most often took the form of direct payments; except in one case, where it took the form of a market sharing agreement. None of the parties submitted the evidence necessary to show that all four conditions for the application of Article 101(3) TFEU had been met.

Under Article 102 TFEU, Servier was found to be dominant on the market for perindopril in the United Kingdom, France, the Netherlands and Poland, for the period starting in 2000 and ending between 2007 and 2009 (depending on the specific national market). The Decision established that Servier put in place a strategy of delaying generic entry by an acquisition of competing technologies in 2004 and the consecutive conclusion of five settlement agreements. This constituted an abuse of a dominant position.

The investigated practices were liable to delay generic entry on the market for perindopril and thus maintain high prices for the drug during many years, to the detriment of consumers and healthcare systems. Generic entry, when it finally happened, resulted in large price drops for perindopril.

4. The Commission's patent settlement monitoring exercise

As announced in the Commission's Communication concluding the SI, it has been considered important to continue monitoring the patent settlements between originator and generic companies over time.¹³ The main objectives of the monitoring exercise are to better understand the use of this type of agreement in Europe and to identify those settlements that delay generic market entry to the detriment of the European consumer possibly in violation of European competition law.¹⁴

As already discussed above, like in any other area of commercial disagreement, the parties concerned have a legitimate interest in finding a mutually acceptable compromise. In particular the parties may prefer to discontinue the dispute or litigation because it is too costly, time-consuming and/or risky as regards its outcome. Settlements are thus a generally accepted, legitimate way of ending private disagreements. They can also save courts and/or competent administrative bodies such as patent offices' time and effort. Therefore, they can have some positive impact in the interest of society.

However, some patent settlements in the pharmaceutical sector may prove to be problematic

¹³ <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>
¹⁴ Commission Communication, p. 20.

from a competition law perspective. The pay-for-delay patent settlements extensively discussed in this document are of particular interest, as they may lead to a delay of generic entry in return for a value transfer by the originator company to the generic company. Other examples of possibly problematic agreements relate to settlements that contain restrictions beyond the exclusionary zone of the patent, meaning that they would reach beyond its geographic scope, its period of protection or its exclusionary scope. Such agreements would not appear to be directly related to the IP rights granted by the patents concerned. Furthermore, problematic agreements include settlement agreements on a patent which the patent holder knows does not meet the patentability criteria. An example of this is a situation where the patent was granted following the provision of incorrect, misleading or incomplete information. Ultimately, it may be the consumer who pays the price for a delay in market entry resulting from such agreements and therefore any benefits to society are more than outweighed by the negative effects of the agreement between potential competitors. In this context, obviously, an assessment of each individual case would be necessary.

4.1. A categorisation of patent settlement agreements

In the SI final report, the Commission proposed a categorisation of patent settlement agreements which has been used for the purpose of this monitoring exercise. Agreements that do not restrict the generic company's ability to market its own product are categorised as A-type, while those limiting generic entry are categorised as B-type. Agreements limiting generic entry are further categorised in two groups: (i) B.I settlements, which comprise those settlements where no value transfer from the originator to the generic company took place; and (ii) B.II settlements which foresee a value transfer from the originator to the generic.

Typically, category A settlements should be unproblematic from a competition law perspective, as they allow immediate market entry by the generic company with its own product (unilateral conduct of the originator company that might have caused generic delay would remain subject to competition law scrutiny).

The same applies to category B.I settlements. Nonetheless, some settlement agreements in this category may attract competition law scrutiny. This may be the case for settlements concluded outside the exclusionary zone of the patent and/or settlement agreements on a patent for which the patent holder knows that it does not meet the patentability criteria, e.g. where the patent was granted following the provision of incorrect, misleading or incomplete information.

By contrast category B.II settlements are likely to attract antitrust scrutiny since they limit access to the market and contain a value transfer from the originator to the generic. Nonetheless, this is not to suggest that agreements falling into this category would always be incompatible with EU competition law. This needs to be assessed on the basis of the circumstances of each individual case.

4.2. Evidence from the monitoring exercise

The last monitoring exercise undertaken by the Commission covered the period of 1 January 2012 until 31 December 2012, i.e. 12 months.¹⁵ It unearthed 183 patent settlement agreements concluded in the EEA. In line with the upward trend described in the previous monitoring reports, the last exercise confirmed the increasing use of patent settlements in the European pharmaceutical sector measured by the number of patent settlements concluded. The annual average of 24 patent settlements concluded in the period covered by the sector inquiry steadily increased to 183 settlements in the year 2012. Also, the number of INNs which were the subject of settlements increased significantly from less than 10 INNs in the first three years of the millennium to more than 40 in 2012. As with the former three exercises, the results of the last monitoring exercise showed that the Commission's investigative activity did not hinder companies from concluding settlements.

The amount of B.II settlements (i.e. settlements which restrict generic entry and show a value transfer from the originator to the generic company) stabilized at a low level. In the period covered by the sector inquiry, B.II settlements represented 22% of all settlements reported, or five settlements per year on average. This percentage decreased steadily over the years to reach 7% in the period of the last exercise or 12 in absolute terms.

The statements of certain stakeholders during the SI that the Commission would be forcing companies to litigate each patent dispute until the end has proved to be unfounded, given the substantial increase in settlements overall. In addition, 93% of the settlements fall into categories not raising prima facie any need for competition law scrutiny. Companies, in most cases, seem to have been able to solve their disputes in a manner that is typically considered unproblematic from a competition law perspective.

¹⁵ All Reports on the Monitoring of Patent Settlements published by the Commission can be found at the following link: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

5. Conclusion

The Commission has been over the last years resolute in enforcing EU antitrust rules in the pharmaceutical sector. This effort has led to the finding of a number of infringements of both Articles 101 and 102 of the TFEU.

The decision on the AstraZeneca case was the first decision by the Commission finding an abuse of dominance in the pharmaceutical sector, constituting an infringement of Article 101 of the TFEU. The Courts upheld the Commission's view that misuse of regulatory procedures, including the patent system, may infringe EU competition rules.

Since the closing of the SI, a number of investigations have been under way concerning agreements whereby an originator used value transfers to induce potential generic competitors not to enter the market. These investigations have already led to two prohibition decisions being adopted by the Commission due to infringement of Article 101 of the TFEU.

Rewards to innovation and effective competition both crucially contribute to patients having access to affordable medicines today and better innovative medicines tomorrow. Misusing regulatory procedures to exclude competitors or paying competitors to stay out of the market at the expense of European citizens are distortions of effective competition that have nothing to do with the legitimate protection of intellectual property: these are illegal practices that the Commission is determined to fight against.

II. Competition in the Distribution of Pharmaceuticals

1. Introduction

The distribution of pharmaceuticals is an essential part of the effort to deliver safe, effective and affordable medicines to patients. An efficient distribution of medicines is instrumental to ensure that patients everywhere in Europe have access to their medications in a timely manner, avoiding shortages, maintaining the optimal qualities of pharmaceutical products and guaranteeing the integrity of the supply chain to prevent the introduction of falsified medicines in it.

In the area of health care, the European Union shares competence with its Member States, the latter being responsible for the organisation and delivery of health services and medical care within their territories. As a consequence, the regulatory environment differs across Member States, for instance with respect to the pricing and reimbursement of medicines, to the restrictions on ownership and operation of pharmacies, and generally to the organisation of pharmaceutical distribution. Nevertheless, in carrying out their responsibilities, Member States and health care stakeholders such as national health services and pharmaceutical companies are affected by EU legislation.

Basic legislation relevant to pharmaceutical distribution includes the principles of Good Distribution Practice (GDP) stated in Directive 92/25/EEC and Title VII on Wholesale Distribution of Medicinal Products in Directive 2001/83/EC¹⁶. Recent developments include the adoption of Directive 2011/62/EU on prevention of the entry into the legal supply chain of falsified medicinal products¹⁷ and the publication in November 2013 of revised Guidelines on GDP of medicines¹⁸. Ultimately, pharmaceutical distribution must be compliant with EC Treaty rules on competition in the Single Market.

2. Market structure of pharmaceutical distribution in the EU

Medicines produced by pharmaceutical manufacturers are dispensed to patients through a variety of channels. Prescription medicines are typically dispensed to patients in retail pharmacies. Non-prescription medicines (over-the-counter, OTC) are sold either in retail pharmacies or, in some countries, also by non-specialised retailers. A significant proportion

¹⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0067:EN:PDF>

¹⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:EN:PDF>

¹⁸ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF>

of prescription and OTC medicines are dispensed and administered to patients in hospital settings. While wholesalers are the main providers of medicines to pharmacies and other retailers, pharmaceutical manufacturers tend to distribute their products directly to hospitals.

2.1. Wholesaling

The majority of countries have a mixture of national and regional wholesalers supplying medicines to retail pharmacies. This typically includes "full line wholesalers" operating at national level that provide the full range of medicines and "short line wholesalers" distributing a limited set of medicines and that often operate at regional level. In most EU countries, national full line wholesalers represent the largest share of the wholesaling market, well above 60% of total pharmaceutical sales. However this is not the case in Greece, Portugal and Spain, where national wholesalers' share stands below 50%. In most countries, wholesalers' activities are subject to public service obligations establishing minimum requirements in terms of frequencies of delivery, product portfolio and geographical reach.¹⁹

2.2. Retailing

While pharmaceutical retailing is typically less concentrated than wholesaling, differences in the degree of pharmacy concentration are significant across EU countries. The number of pharmacies goes from one pharmacy per every ten thousand inhabitants in Denmark, Sweden, Slovenia and the Netherlands to more than five in Malta, Cyprus and Bulgaria, and almost eight in Greece. Most countries however have between two and four pharmacies per every ten thousand inhabitants. Country-specific regulations on pharmacy ownership and on the establishment of new pharmacies partially explain such differences.

Sixteen EU countries have some form of regulation of pharmacy establishment, often in the form of geographic and demographic criteria to limit the density of pharmacies. Thirteen countries regulate pharmacy ownership. The most restrictive ownership regulations are found in France, Greece, Italy and Spain, where only pharmacists may be owners (albeit in some countries as co-owners) and may only own one pharmacy.²⁰

Entry regulations exist in many EU countries for various professional fields, not only

¹⁹ Figure 3.1 in *The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices*. EMINET, March 2011.

²⁰ (http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/structimpact_pharmaprices_032011_en.pdf)
Ibid., Figure 3.3.

pharmacies; including accountancy, legal and financial advice, architecture or engineering.²¹

2.3. Horizontal and vertical integration

The distribution chain has witnessed considerable consolidation in the past decade, which has manifested itself both through horizontal but also vertical integration. The degree to which consolidation has taken place often depended on national regulations.

In the last decade, nearly all EU countries have seen mergers in the wholesale sector and a decline in the number of operating wholesaler companies. On the retail side, pharmacy chains are becoming more prevalent. Some form of pharmacy chain is allowed in 19 EU countries. For instance, in Estonia, Lithuania and the UK more than 80% of the pharmacies belong to a chain. However, the diverse retail market structures and regulatory environments across the EU make it difficult to identify common patterns. The retail segment continues to be much fragmented in other countries where regulation is more restrictive on pharmacy ownership and establishment, like France, Greece, Italy and Spain. However, even in these cases there has been a trend towards joint procurement through cooperatives of pharmacies.

Vertical integration between wholesalers and retailers has also been in the rise, again constrained by certain regulations limiting ownership of pharmacies to pharmacists. Vertical integration is allowed, either with or without restrictions in 10 EU countries.²²

2.4. Direct-to-pharmacy (DTP) distribution

It is increasingly common to observe that pharmaceutical manufacturers deliver medicines directly to retail pharmacies, not only to hospitals. While the majority of sales continue to be supplied to pharmacies by wholesalers, in a number of EU countries the proportion of sales supplied to pharmacies directly by the manufacturer have significantly increased. They represent above 10 per cent of pharmacy sales in Denmark, Greece, Ireland, Luxemburg, Netherland and UK, and above 20% in the Czech Republic, France and Italy.²³

DTP distribution can take place via a variety of schemes. It is not uncommon for

²¹ *Economic impact of regulation in the field of liberal professions in different Member States*. IHS for DG Competition, January 2003, p. 51.

²² *The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices*. EMINET, March 2011, p. 31.

²³ http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/structimpact_pharmaprices_032011_en.pdf *ibid.*, p. 32.

manufacturers to have set up their own wholesale distribution channel for part of the portfolio. An alternative model is the so-called "sole agency", where the manufacturer sells directly to their customers with an exclusive wholesaler acting as a logistics provider. An intermediate option is the Reduced Wholesaler Model (RWM) schemes, in which the manufacturer selects a limited set of wholesalers (typically up to 3).²⁴

Agency models limit wholesalers' ability to set their own commercial strategy and offer discounts, as they actually never own the stock. Less extreme models like RWM may also constraint wholesalers' decisions to some extent, depending on the terms of the agreement with the manufacturer. A consequence of these developments is a less clear-cut distinction between wholesalers and logistic providers than it had usually been the case.

3. The remuneration of pharmaceutical distribution

In recent years there has been considerable focus on the impact of the distribution chain on the total cost of prescription pharmaceuticals. Regulators have introduced changes in the remuneration of pharmaceutical wholesalers and pharmacies, with the aim of reducing the cost of distribution and increasing the efficiency of the distribution chain. The regulation of pharmaceutical prices, margins, and reimbursement and dispensation conditions creates incentives that distort the behaviour of market players, including wholesalers and pharmacists. The efficiency of market outcomes produced by such regulations remains in most of the cases a question to be assessed empirically.

The majority of EU countries regulate pharmaceutical wholesale and retail margins. Regulated margins can take different forms, including regressive mark-ups, proportional mark-ups and flat fees. Regressive mark-ups, the most common in the EU for both wholesaling and retailing, are typically designed as a percentage on ex-factory price that decreases as the price increases. Regulated margins are typically applied to reimbursable medicines, while they are less commonly applied to non-reimbursable medicines.

Data shows that most EU countries have average wholesale margins between 5% and 10%, although there is significant cross-country variability and the full range goes from the minimum observed margin of 3% in Sweden to the maximum of 23% observed in the Netherlands.²⁵ With respect to pharmacy margins, data shows most countries to apply

²⁴ Ibid., p. 33-34.
²⁵ Ibid., Figure 4.1.

margins ranging between 18% and 25%.²⁶

Evidence suggests that wholesalers often offer a proportion of their allowable margin as a discount to pharmacies, to the extent that national regulations allow for it. The size of these discounts appears to be related to the relative bargaining power of wholesalers and pharmacies. Pharmacy chains and pharmacies' purchasing groups may have a greater bargaining power than single pharmacies, resulting in higher discounts obtained from wholesalers. On the contrary, evidence shows that maximum regulated margins for reimbursable medicines tend to be fully utilised by retail pharmacies when dispensing to patients, especially in Western European countries. As a result, retail pharmaceutical prices are largely homogeneous across pharmacies within the same country and price competition among retail pharmacies is therefore limited.²⁷

In some countries, a significant proportion of pharmacy income comes from fixed fees, notably in Belgium, Denmark, Ireland, Netherlands and the UK. Usually these are dispensing fees linked to the volume of sales, not to pharmacy performance on value-added services to patients. There is an ongoing debate about the efficiency-enhancing incentives the could be generated by introducing fees for value-added services offered by pharmacies, like patient advice or therapy management, but there has been little regulatory development so far.²⁸

4. Changing competitive dynamics in wholesaling and retailing

Developments in IT and logistics have triggered significant changes in the way wholesalers and pharmacies operate, with an impact in the competitive dynamics of the sector. Full line wholesalers have traditionally played a fundamental role in offering retail pharmacies the option of working with a few providers instead of a myriad of manufacturers, thus reducing their administrative burden and operating costs. However, having multiple providers has become less burdensome for pharmacies with recent advancements in IT and logistics. Also pharmacies' consolidation has increased their logistic capabilities. Manufacturers have identified this as an opportunity and show increased interest in establishing direct vertical links with retail pharmacies. This has resulted in DTP accounting for increasing shares of pharmacy sales, as discussed above.

Regulated distribution margins calculated as a proportion of the medicines prices imply that

²⁶ Ibid., Table 4.2.

²⁷ Ibid., p. 40-48.

²⁸ Ibid., p. 45.

distributors obtain higher remuneration from supplying higher-price medicines. As a result, wholesalers and pharmacies obtain a large proportion of their remuneration from a limited number of medicines with high prices. For instance, data for France shows that wholesalers generate 80% of their revenue from only 12% of prescription medicines, while the remaining 88% generate just 20% of their revenue. This cross-subsidisation from high-price towards low-price drugs makes the current distribution models sustainable. To the extent that manufacturers decided to supply high-price drugs directly to pharmacies, wholesalers might find it increasingly difficult to cover the costs of meeting their public service obligations with respect to low-price drugs on which they make little profit.²⁹

Wholesalers have faced increasing competitive pressure in recent years as a result of a number of developments, including advancements in IT and logistics, increased bargaining power of consolidated retailers, as well as a more active role of manufacturers in the distribution of medicines. Wholesalers have responded to these challenges granting larger discounts, seeking economies of scale through consolidation of existing entities. New distribution models like the sole agency model or the RWM are also redefining the traditional role that used to be played by full line national wholesalers.

Although the diverse retail market structure and regulatory environment across the EU makes it more difficult to identify common patterns, also the shape and role of pharmacies is adapting to this changing environment. This has included consolidation in some countries, the development of joint procurement in others. Competition among pharmacies may also lead to enhancing their role in health promotion, prevention, disease management and monitoring.

5. The impact of distribution on generic competition

Beyond competition among pharmaceutical distributors and its outcomes in terms of the cost and quality of their activities, the way in which medicines are distributed has also an impact on competition among pharmaceutical manufacturers. In particular, the design of regulations on pharmacy distribution has an impact on generic competition and uptake after patent expiry.

The analysis produced by the European Commission in the context of the Pharmaceutical Sector Inquiry showed that innovative drugs under patent protection typically enjoy higher

²⁹ Ibid., p. 41.

prices than off-patent drugs facing generic competition. It also showed that often branded off-patent drugs manage to maintain higher prices than generic substitutable drugs well after patent expiry. Given the prevalent structure of distribution margins, this implies that wholesalers and pharmacies obtain higher remuneration from selling patented drugs and branded off-patent drugs than they do from selling generic drugs.³⁰

Distributors therefore have a financial incentive to sell more expensive drugs. This has been identified as one of the features that may hinder the uptake of generic medicines in EU countries. The introduction of regressive margins instead of purely proportional margins has aimed at reducing this incentive, but not to the extent of fully counterbalancing it. Only fixed fees whose value is independent from the medicines prices could in fact fully counterbalance it. A number of EU countries have attempted to address this issue by introducing an obligation by the pharmacist to dispense always the cheapest generic version of a drug or by limiting reimbursement to the price of the cheapest versions of a drug. In the former, the formal obligation to dispense the cheapest drug should be the counterbalancing factor. In the latter, the patient is obliged to pay for the part of the price above the reimbursement level, in such a way that the patient has a financial incentive in the opposite direction to that of the pharmacist. Evidence shows that both types of measure have a positive effect on generic uptake.³¹

6. Concluding remarks from a patient and payer perspective

The structure of medicines distribution differs significantly across EU countries. A variety of models are used to achieve the fundamental objective of delivering safe, effective and affordable medicines to patients, complying with basic EU legislation in the field. Pharmaceutical distribution is regarded as part of the healthcare system and therefore subject to certain public obligations that are established by national regulators.

Recent developments in the sector may be seen as encouraging both from a payer and from a patient perspective: advancements in IT and logistics reducing operational costs, wholesalers facing increased competitive pressure, consolidation delivering efficiencies through economies of scale. These developments are already redefining the roles traditionally played by wholesalers and retail pharmacies.

³⁰ Pharmaceutical Sector Inquiry Final Report, European Commission, July 2009, Figures 25 and 28.

³¹ Pharmaceutical Sector Inquiry Final Report, European Commission, July 2009, p. 86.

Greater efficiency in the distribution of medicines will be achieved if ultimately patients get better services at a lower cost to payers. This is an objective that the Commission shares with national governments and which requires both well-designed regulation.