COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 8.7.2009
COM(2009) 351 final

COMMUNICATION FROM THE COMMISSION

Executive Summary of the Pharmaceutical Sector Inquiry Report

{SEC(2009) 952}

COMMUNICATION FROM THE COMMISSION

Executive Summary of the Pharmaceutical Sector Inquiry Report

1. THE SECTOR INQUIRY AND THE WIDER CONTEXT

The pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines. On average approximately € 430 was spent on medicines in 2007 for each European and this amount will likely continue to increase as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices.

This report is part of well-established Commission policies and initiatives relevant to the pharmaceutical sector including the Lisbon Strategy, the Commission's Industrial Property Rights Strategy[1], the Communication on a Renewed Vision of the Pharmaceutical Sector[2] and the Innovative Medicines Initiative[3]. It should also be viewed in parallel with the Commission's regulatory activities addressing, in particular, the safety, quality and efficacy of medicines[4], the transparency of national pricing and reimbursement procedures[5] and the protection of intellectual property rights. Indeed, given the importance of the pharmaceutical industry for economic growth and employment, as well as its role for public health, the Commission is committed to pursuing policies that create an environment conducive to ensuring the viability of this sector.

The sector inquiry therefore ties in with other Commission initiatives aimed at providing European patients with safe, effective and affordable medicines, while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry[6].

---

1 Commission Communication of 16 July 2008 on an Industrial Property Rights Strategy for Europe - COM(2008) 465.

2 See, in particular, Commission Communication of 10 December 2008 - COM(2008) 666, 10.12.2008: Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector.

3 The Innovative Medicines Initiative is a Public-Private Partnership (PPP) between the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Communities represented by the European Commission. See: http://imi.europa.eu/index_en.html.

4 See, for instance, Regulation (EC) No 726/2004 and Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC.

5 Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems.

6 See, further to the above, the High Level Pharmaceutical Forum (http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf), as well as the ongoing market monitoring reviews.

The Key Role of Innovation

Innovation is of key importance for the pharmaceutical sector. Innovation in human medicines has enabled patients to benefit from treatments that were unimaginable a few decades ago. Moreover, the lack of adequate treatment for many diseases requires continuous innovative efforts in order to find new medicines. Without the very significant R&D efforts of originator companies and other stakeholders (e.g. universities) these benefits would not be possible.

Intellectual property rights are a key element in the promotion of innovation. The protection of intellectual property rights is important for all sectors of economic life and is paramount to Europe's competitiveness. However, it is particularly important for the pharmaceutical sector because of the necessity to address current and emerging health problems and the long life cycle of products (including long development periods). The pharmaceutical sector in the EU indeed has one of the highest investments in R&D in Europe and relies significantly on intellectual property rights to protect innovation. The exclusivity periods granted through patent law and other mechanisms (SPC, data exclusivity) provide incentives to originator companies to continue innovating.

The Commission, which is committed to the promotion of innovation through industrial property rights, including patents, as stated in the 2007 Patent Communication[7] and the above mentioned 2008 Industrial Property Rights Strategy Communication, underlines the need for high quality patents granted in efficient and affordable procedures and providing all stakeholders with the required legal certainty.

The Need to Keep Public Budgets under Control

At the same time, it is generally acknowledged that public budgets, including those dedicated to cover health expenditure, are under significant constraints. Competition, in particular competition provided by generic medicines, is essential to keep public budgets under control and to maintain widespread access to medicines to the benefit of consumers/patients.

In this context the Final Conclusions and Recommendations of the High Level Pharmaceutical Forum[8] welcomed the shared understanding among stakeholders that pricing and reimbursement policies need to ensure a.o. control of pharmaceutical expenditure for Member States. In this respect it was acknowledged that generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines[9]. As stated in the Communication on a Renewed Vision of the Pharmaceutical Sector[10], "[m]any Member States recognise that generic medicines play an important role in helping to limit their healthcare expenditure in their

---

7 Commission Communication « Enhancing the patent system in Europe » - COM(2007) 165.

8 http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf.

9 High Level Pharmaceutical Forum: Guiding principles for good practices implementing a pricing and reimbursement policy (http://ec.europa.eu/pharmaforum/docs/pricing_principles_en.pdf).

10 Commission Communication of 10 December 2008 - COM(2008) 666, 10.12.2008: Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector.

reimbursement and prescribing practices. Competition with off-patent products enables sustainable treatment of more patients with less financial resources. The generated savings create financial headroom for innovative medicines. All actors should therefore ensure that generics can enter the market after expiry of patent and data exclusivity protections and compete effectively".

In particular generic medicines should reach the market without unnecessary or unjustified delay. Member States that want to fully benefit from the potential budget savings brought about by generic products also need to reflect about policies that facilitate speedy generic uptake in volume terms and effective price competition among generic producers.

Recent Changes in the Sector

The pharmaceutical industry is undergoing significant changes. Several "blockbuster" medicines (i.e. medicines whose annual global turnover exceeds US$ 1 billion), which account for a substantial part of the sales and profits of large originator companies, have lost patent protection in recent years and more will do so in the coming years. At the same time, in spite of increasing investments in R&D, it appears to be a challenge for originator companies to refill the product pipeline and the number of novel medicines reaching the market has been decreasing. Combined with other factors, this makes originator companies increasingly dependent on the revenues from their existing best-selling products and they inevitably wish to maintain these for as long as possible. In some years the decline in novel medicines reaching the market will also affect the generic industry, which will have less generic products to launch.

An intensified consolidation in the sector has been observed in recent years. Originator companies have undertaken various acquisitions of both originator companies and generic companies. Smaller originator companies, often biotech based, can deliver potential novel medicines to fill the gap in the pipeline of originator companies. In parallel, many larger originator companies are investing in the growing generics market by taking over generic players. This helps them to diversify their risk structure and can create opportunities to enter into new geographic markets. Finally, various mergers have taken place between generic companies, which may be driven by considerations on economies of scale and opportunities in new geographic markets. The aim of merger control in the EU is to allow these types of consolidation as long as they do not result in a significant impediment to effective competition.

Scope of the Inquiry

Given the importance of a well-functioning pharmaceutical sector and the presence of certain indications that competition in the pharmaceutical market in the European Union might not be working well, the Commission launched a sector inquiry into pharmaceuticals on 15 January 2008[11]. In particular, the inquiry sought to examine the reasons for observed delays in the entry of generic medicines to the market and the apparent decline in innovation as measured by the number of new medicines

[11] Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514).

coming to the market. Sector inquiries allow the Commission to gather information for giving effect to Articles 81 and 82 of the EC Treaty.

Taking into account that sector inquiries are a tool under EC competition law[12], the inquiry's main focus is company behaviour. The inquiry concentrates on those practices which companies may use to block or delay generic competition as well as to block or delay the development of competing originator products. The primary focus of the inquiry is thus the competitive relationship between originator and generic companies and amongst originator companies. To this end the Commission selected 43 originator companies and 27 generic companies for in depth analysis. They represent 80 % of the relevant turnover in the EU and are typically larger scale companies active in more than one Member State.

As the industry is strongly regulated and the behaviour of companies needs to be assessed in the context of the existing regulatory framework, the sector inquiry also looked in broad terms at aspects of the regulatory framework, its implementation and alleged shortcomings reported by stakeholders. In this respect it concentrated on the legislation governing patents, marketing authorisations and pricing and reimbursement.

Product scope: The inquiry concerns prescription medicines for human use. Medicines sold over the counter (OTC), medicines for animal use, medical devices and health services are not subject to the inquiry. A sample of 219 substances was selected for the in-depth investigation. The selected molecules accounted for nearly 50% of the overall turnover of prescription medicines in the EU in 2007.

Geographic scope: The geographic scope of the inquiry is the 27 Member States currently forming part of the European Union. For certain sections the analysis was limited to a more narrow selection of Member States. A comparison with other geographic regions was only possible to a limited extent. This also implies that the inquiry and its findings have mainly relevance for the EU and, as such, its findings cannot be extrapolated to other areas of the world with diverging regulatory regimes, e.g. on intellectual property rights.

Time scope: The period of inquiry is 2000 to 2007, but for certain sections updates up to June 2008 were requested. It has to be kept in mind that during this period a number of changes occurred, such as the enlargement of the European Union to 25 and later to 27 Member States. Moreover significant changes in the pharmaceutical regulatory framework entered into force in 2005, which had a.o. the objective to facilitate generic entry[13], e.g. the introduction of the so called Bolar[14] provision.

---

12 Article 17(1) 1st paragraph of Council Regulation 1/2003 reads: "Where the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market, the Commission may conduct its inquiry into a particular sector of the economy or into a particular type of agreements across various sectors. In the course of that inquiry, the Commission may request the undertakings or associations of undertakings concerned to supply the information necessary for giving effect to Articles 81 and 82 of the Treaty and may carry out any inspections necessary for that purpose."

13 See, for instance, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC.

14 Article 10(6) of Directive 2001/83/EC as amended by Directive 2004/27/EC: this provision was to be transposed by Member States by 31 October 2005. Prior to the introduction of the Bolar provision in the

Some of the new rules (namely the new harmonised rules on data and marketing exclusivity) will only take effect in practice in 2013 as the new periods of protection apply to originator products applied for and authorised after the coming into effect of these rules in 2005.

Terminology: In order to fully capture the competitive process from a commercial perspective, the report makes use of the industries' terminology and concepts to describe certain types of patents, products and related strategies. It is underlined that these terms and concepts are not defined in patent legislation. By using them in the context of the inquiry it is not intended to suggest that these terms and concepts should be relevant under patent law. With the same token no negative connotations, in particular with regard to terms like "primary"/"secondary" patents, "defensive patenting" and "patent clusters" or "patent thickets" is intended, as applications are to be evaluated on the basis on the statutory patentability criteria (i.e. novelty, inventive step and industrial applicability), and this is irrespective of the stage in which applications are made, the intent of applicants in applying for patent rights or how the patents are addressed in the company's internal strategy documents. The notion of “secondary patent" should therefore not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – they follow the primary patent. As regards defensive patenting, it is an inherent feature of a patent system to grant exclusive rights. The notion of "defensive patents" should therefore not be understood to mean that these patents are of a lower quality or value, but it tries to capture a classification made in industry for this type of patents from a commercial perspective.

Issues only partly covered or not covered: In line with the opening decision the inquiry does not address in detail potential shortcomings in the distribution chain, which is currently subject to a market monitoring exercise[15]. Nor does it address barriers to parallel trade in the pharmaceutical sector[16]. Competition between generic companies, which broadly speaking takes place on the basis of price, was not in the focus of the sector inquiry, as any price fixing and/or market allocation agreements between competitors would be caught by Article 81 EC and the inquiry was - under the present circumstances – not deemed to be the adequate tool to analyse potential shortcomings in this part of the market. However, national policies that have an impact on generic uptake and prices are addressed in the report. Finally, as the legal basis for launching a sector inquiry is EC competition law, the sector inquiry did not

---

EU regulatory framework, pre-patent-expiry development was not regulated at EU level. Consequently, generic manufacturers carried out their product development and related testing in countries where the basic patent had already expired or where such protection did not exist, outside the EU or in European countries where a Bolar-type provision existed or in EU Member States where experimental work was in certain cases permitted (cf. section B.2.2.1 of the technical annex).

15 See: Commission Staff Working Document on 'Market Monitoring: State of Play and Envisaged Follow-Up', at: http://ec.europa.eu/economy_finance/publications/publication13688_en.pdf (see in particular Section 4 par. 5 on monitoring the retail sector); Commission Staff Working Document on 'The Single Market Review: one year on', at: http://ec.europa.eu/internal_market/strategy/docs/smr_oneyear_en.pdf (see in particular p. 11 par. 3 and the following box on market monitoring as part of the follow-up to the 2007 Single Market Review).

16 See on the application of competition law to parallel trade in the pharmaceutical sector the judgment of the ECJ of 16 September 2008 (Joined Cases C-468/06, C-469/06, C-470/06, C-471/06, C-472/06, C-473/06, C-474/06, C-475/06, C-476/06, C-477/06, C-478/06 Sot. Lélos kai Sia). See also pending Case C-501/06 P GlaxoSmithKline Services v Commission.

analyse which other important factors – apart from company behaviour – could have contributed to a decline in innovation as measured by fewer novel medicines reaching the market. Reasons given by the industry include increased scientific complexities, high attrition rates in late state development due to regulatory risk aversion and uncertainty about financial awards.

Market monitoring in the pharmaceutical sector: In addition to the sector inquiry, the Commission currently carries out further monitoring of the pharmaceutical sector[17], whose objective is to provide a comprehensive, comparative and macro-level analysis of the EU market for pharmaceuticals. These market monitoring exercises will cover some of the areas not addressed by the sector inquiry such as the distribution chains or trends in access to medicines or trends in innovation spending in the EU.

Competition law guidance: It is important to underline that – whilst the report primarily analyses company behaviour – it does not identify individual cases of wrongdoing or provide any guidance on the compatibility of the practices examined with the EC competition rules. It provides the Commission however with relevant context and a factual basis for deciding whether and what further action is needed, including enforcement action.

Steps of the inquiry

Following the launch of the inquiry the Commission services carried out upfront inspections and gathered data and other information on the basis of requests for information from a wide range of stakeholders, most prominently from the selected originator and generic companies.

The Commission also consulted widely with stakeholders such as industry associations, representatives of consumers and patients, insurance companies, associations of doctors, pharmacists and hospitals, the European Patent Office (EPO) and national patent offices, national competition authorities, and other national authorities.

The Commission presented its Preliminary Report on the pharmaceutical sector inquiry[18] on 28 November 2008. It reached the preliminary conclusion that behaviour and practices of the originator industry contributed to generic delay as well as to the difficulties in innovation while pointing to the existence of other possible factors, such as regulation in the sector.

In the framework of the public consultation on the report, more than 70 submissions from interested parties were received[19]. Stakeholder responses in summary are:

Consumer representatives, the generic industry and the health insurance sector underline the uniqueness of the report and submit that the findings confirm their

---

17 See: Commission Staff Working Document on 'Market Monitoring: State of Play and Envisaged Follow-Up', at: http://ec.europa.eu/economy_finance/publications/publication13688_en.pdf (see in particular section 4 par. 6 on the pharmaceutical sector).

18 Pharmaceutical Sector Inquiry, Preliminary Report, DG Competition Staff Working Paper, 28.11.2008.

19 The non-confidential versions of these responses are available at: http://ec.europa.eu/competition/consultations/2009_pharma/index.html.

concerns that generic entry is not occurring as quickly as it should and that less novel medicines reach the market addressing unmet patients' needs. They call for urgent action to remedy the problems highlighted in the preliminary report.

Originator industry representatives, partly supported by representatives of law firms and patent attorneys, by numbers the largest amount of submissions, argue that the Preliminary Report does not provide evidence that companies' practices hinder innovation, which leads to a decline in innovation. They also suggest that delays to generic entry cannot be attributed to the behaviour of originator companies, but consider factors related to the regulatory framework to be most important for delays. They finally suggest that the Commission should investigate other shortcomings in the market, e.g. the alleged lack of competition between generic companies.

The *European Patent Office* provides input on the functioning of the European patent system and draws attention to the line between IP law and competition law as drawn by the ECJ. In particular, it argues against a scrutiny of the intent of applicants in applying for patent rights for purposes of competition law.

Despite the differences in views on some of the findings set out in the Preliminary Report, there is broad consensus among stakeholders on the need to establish a Community patent and for a unified specialised patent litigation system in Europe.

The key findings of the sector inquiry can be summarised as follows.

2. MARKET CHARACTERISTICS AND IMPACT OF GENERIC ENTRY

2.1. Main Market Features

2.1.1. Market Structure

The pharmaceutical sector is highly regulated and R&D driven. On the supply side, there are two types of companies. Originator companies are active in research, development, management of the regulatory process for new products including the clinical trials needed for marketing authorisation, manufacturing, marketing and supply of innovative medicines. Their products are usually subject to patent protection, which, on the one hand, provides a compensation for the often very high costs spent on innovation and, on the other hand, makes information on inventions public. The protection is limited in time, encouraging the company to bring the innovation to market as quickly as possible and ensuring that the company continues to innovate and bring forward future innovative products. The second category of companies, manufacturers of generic products, can enter the market with medicines that are equivalent to the original medicines, upon patent expiry of the pre-existing original products and when the data exclusivity period for the originator product expired. Their prices are typically much lower than those of the originator products. This helps containing public health budgets and ultimately benefits consumers. The market share of generic medicines varies significantly between Member States.

From 2000 – 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide[20] (approximately 1.5% of turnover was spent on basic research to identify potential new medicines and 15.5% of turnover was spent on developing the identified potential medicines through trials into products sufficiently safe and efficacious to be marketed)[21]. Expenditure on marketing and promotional activities accounted for 23% of their turnover during the period. In the year 2007 manufacturing costs accounted for 21% of originator companies' total turnover. Originator companies rely, to a significant degree, on the acquisition of compounds from third parties. In 2007 about 35% of originator companies' molecules where marketing authorisation was pending had been acquired or in-licensed. Some of these third parties are small and medium sized enterprises, e.g. in the biotechnology sector. The largest cost block of generic companies in 2007 was manufacturing (51%), followed by marketing (13%) and R&D activities (7%), showing their different cost structure.

On the demand side, the pharmaceutical sector is unusual in that, for prescription medicines, the ultimate consumer (the patient) is not the decision maker. Decisions are generally made by the prescribing doctors, and in certain Member States, the pharmacist also plays a role. Yet, neither the patient, nor the prescriber or the dispenser directly bear most of the costs, as these are generally covered and/or reimbursed largely, or even wholly, by national health (insurance) schemes. The pharmaceutical sector is also unusual in that prices are most often the result of a regulated decision-making process, involving nevertheless negotiations between stakeholders. Where this is not the case, i.e. in countries with so-called free pricing, prices are dependent on the regulated reimbursement decisions. Because of this structure, doctors, pharmacists and patients are usually not very price sensitive for prescription medicines, although various mechanisms to control prescription medicine budgets do exist[22].

2.1.2. Impact of Generic Entry

The sector inquiry looked at the economic conditions surrounding generic entry. The inquiry found that about half of the medicines subject to in depth investigation faced generic entry within the first year after loss of patents (including SPC) and data exclusivity (EU average). Measured in value terms, these medicines represent about 70% of sales (sales value in the year of expiry).

It took more than seven months, on a weighted average basis, for generic entry to occur once originator medicines lost exclusivity. For the highest selling medicines, for which rapid entry matters most, it took four months on average before market entry[23]. However, considerable variations exist across Member States and across medicines.

---

20 The originator companies subject to the inquiry confirmed in the course of the sector inquiry that they carry out research on a global scale.

21 This figure includes failed R&D efforts.

22 This factor has to be kept in mind when comparisons are made to, for example, the United States situation, where pricing and regulatory conditions are quite different.

23 In those cases where data exclusivity under pharmaceutical law expired after patent protection period including SPC (about 7% of the cases in the sample), the above calculations should be considered in the light of the legal provisions of Community law on data exclusivity relevant during the period covered

Delays are important as the price at which generic companies enter the market was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price. Also the prices of originator products appear to drop following generic entry. The market share (in volume terms) of the generic companies was about 30% at the end of the first year and 45% after two years. In other words, any delay will have a significant cost / revenue impact.

In markets where generic medicines become available, average savings to the health system (as measured by the development of a weighted price index of originator and generic products) are almost 20% one year after the first generic entry, and about 25% after two years (EU average). The inquiry points to considerable differences, however, in the effect of entry of generics in the various EU Member States and across medicines.

In relation to a sample of medicines analysed in the period 2000 to 2007, the report estimates that savings due to generic entry could have been 20% higher than they actually were, if entry had taken place immediately following loss of exclusivity. According to the in-depth analysis of this sample, the aggregate expenditure amounting to about € 50 billion for the period after loss of exclusivity would have been about € 15 billion higher without generic entry (evaluated at constant volumes). However, additional savings of some € 3 billion could have been attained, had entry taken place immediately.

Econometric analysis suggests that a number of factors have an influence on the observed pattern and effect of generic entry, e.g. the turnover of the originator medicines before the expiry of the patent/data exclusivity or the regulatory environment. For instance, Member States which oblige pharmacists to dispense the cheapest generic medicines whenever possible appear to show earlier entry and greater savings for their health budgets. Likewise, generic uptake seems to be faster and ultimately generic prices seem to decrease more in Member States which do not oblige the generic companies to respect a certain price cap (e.g. a fixed percentage of the originator product price).

3. MAIN FINDINGS

3.1. Products and Patents

The pharmaceutical sector is one of the main users of the patent system. The number of pharmaceutical-related patent applications before the EPO nearly doubled between 2000 and 2007. Patents concerning the active substances are also referred to by the industry as "primary patents" because they relate to the first patents for their

---

by the inquiry, which in practice would not have allowed for generic market entry at the point of the expiry of data exclusivity. The rules were amended in 2004 so that, as regards originator products applied for and authorised under the new rules, generic applications may be submitted two years in advance of the loss of exclusivity, but the effects of the amendment will only be felt in 2013 as the new periods of protection apply to originator products applied for and authorised after the coming into effect of these rules in 2005. It should be kept in mind that the sector inquiry measured the time between loss of exclusivity and actual generic market entry; the delays established might have a number of reasons, including regulatory factors, logistics etc.

medicines. Further patents for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations are referred to by the industry as "secondary patents"[24]. In general, blockbuster medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product, also after product launch. Occasionally they show an even steeper increase at the end of the protection period conferred by the first patent. In patent litigation cases originator companies often rely on patents that were not yet filed when their product in question was launched.

3.2. Competition between Originator and Generic Companies – The Issues

The findings indicate that originator companies use a variety of instruments to extend the commercial life of their medicines. The results of the sector inquiry suggest that the behaviour of companies contributes to the generic delay.

3.2.1. Patent Filing Strategies

The findings of the inquiry suggest that in recent years originator companies have changed their patent strategies. In particular, strategy documents of originator companies confirm that some of them aimed at developing strategies to extend the breadth and duration of their patent protection.

Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice. Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines[25].

In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1 300 patents and/or pending patent applications across the Member States[26]. Despite the lower number of underlying patent families based on EPO applications, looking from a commercial perspective, a challenger may, in the absence of a Community patent, need to analyse and possibly confront the sum of all existing patents and pending patent applications in those Member States in which the generic company wishes to enter[27].

When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their

---

[24] As pointed out above, patent law does not make a distinction between "primary" and "secondary" patents, and patents need to be evaluated on the basis of the statutory patentability criteria, not on the basis of the stage in which applications are made. The notion of “secondary patent” should therefore not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – they follow the primary patent.

[25] All patent applications do, however, need to be evaluated on the basis of the statutory patentability criteria by the patent offices, not on the basis of underlying intentions of the applicant. For terminology, see above.

[26] The inquiry confirmed that the average number of patents and patent applications for the top selling medicines is 140% higher (i.e. 237) than the average of the overall sample (98.5).

[27] The adverse effects of the current situation would be addressed by the rapid adoption of the Community patent and its consequent use by stakeholders.

ability to enter the market[28]. Statements admit in internal documents collected in the context of the sector enquiry point at the awareness by patent holders that some of their patents might not be strong.

A second instrument used by originator companies could be identified as filing voluntary "divisional patent" applications, most prominently before the EPO where most patent applications in the pharmaceutical sector are filed. Voluntary divisional patent applications, which are foreseen in patent law as a legitimate way to split an (initial) parent application, cannot extend the content of the original application nor the protection period. But they can extend the examination period of the patent office, as the examination of divisional applications continues even if the parent application is withdrawn or revoked, which, under certain conditions, can add to the legal uncertainty for generic companies. On 25 March 2009, the EPO took measures that limit the possibilities and time periods during which voluntary divisional patent applications can be filed[29].

3.2.2. Patent-Related Exchanges and Litigation

Enforcing patent rights in court is legitimate and a fundamental right guaranteed by the European Convention on Human Rights: it is an effective means of ensuring that patents are respected. Like in any other industry the inquiry's findings show, however, that litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

Taking into account the 219 molecules in the sample, originator and generic companies identified at least 1 300 patent-related out of court contacts and disputes concerning the launch of generic products in the period 2000 to 2007. The vast majority of disputes were initiated by the originator companies, which most often invoked their primary patents, e.g. by sending warning letters.

The number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007. In total, 698 cases of patent litigation between originator companies and generic companies were reported in relation to the medicines investigated.

Of these, 223 cases were settled, and the courts rendered final judgements in 149 cases. The remaining 326 litigation cases were either pending or withdrawn. Whilst the originator companies initiated the majority of the cases, generic companies won 62% of the 149 cases. The average duration of the court proceedings was 2.8 years, but varied considerably between Member States, from just over six months to sometimes more than six years.

---

[28] This concerns, for instance, cases where generic companies may have concrete grounds to doubt the validity of a particular patent or consider that a pending patent application does not meet the criteria for patentability.

[29] See the Decision of the Administrative Council of the European Patent Organisation of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09) at: http://www.epo.org/patents/law/legal-texts/decisions/archive/20090325.html.

In contrast to the primary patents invoked in the pre-litigation phase, originator companies mainly invoked secondary patents during litigation.

In 30% of the cases litigation was initiated between the same parties in more than one Member State with respect to the same medicine. In 11% of the final judgments reported, two or more different courts in different EU Member States gave conflicting final judgments on the same issue of patent validity or infringement.

Originator companies asked for interim injunctions in 255 cases, and were granted such injunctions in 112 cases. The average duration of the interim injunctions granted was 18 months. In 46% of the cases in which injunctions were granted the subsequent court proceedings in the main case ended either with final judgments favourable to the generic company, or settlements which appear to be favourable to the generic company as they allowed early entry for the generic company and/or foresaw a value transfer to it. In addition there were a number of further patent settlements, for which a final classification (i.e. favourable to the generic or the originator company) was not possible.

The total cost of patent litigation in the EU relating to the 68 medicines on which litigation was reported for the period 2000 – 2007, is estimated to exceed € 420 million, of which a significant proportion could have been saved, if the cross-border duplication of cases linked to the absence of a Community patent and a specialised patent litigation system could have been avoided.

3.2.3. Oppositions and Appeals

The sector inquiry confirms that the opposition rate (i.e. the number of oppositions filed per 100 granted patents) before the EPO is consistently higher for the pharmaceutical sector[30] (about 8%) than it is in organic chemistry (about 4%) and across all sectors (overall EPO average: about 5%). Based on the information gathered, generic companies almost exclusively opposed secondary patents. In the cases where they opposed, generic companies prevailed in approximately 60% of final decisions rendered by the EPO (including the Boards of Appeal) in the period 2000 to 2007 and the scope of the originator patent was restricted in another 15% of the cases.

However, on average, it took more than two years to obtain approximately 80% of final decisions (including appeal procedures). Whilst it is acknowledged that opposition and appeal procedures – from a procedural point of view – are separate procedures, from a commercial perspective, the time until the final decision is taken – be it in opposition or appeal – is relevant. The duration of the procedures considerably limits the generic companies' ability to clarify the patent situation of potential generic products in a timely manner[31].

---

30 The calculation is based on the closest available proxy for the pharmaceutical sector.

31 EPO acknowledges the importance of timely proceedings and recalls its efforts to improve the situation. See p. 5 of "EUROPEAN COMMISSION PHARMACEUTICAL SECTOR INQUIRY PRELIMINARY REPORT – 28 November 2008, COMMENTS FROM THE EPO" at: http://ec.europa.eu/competition/consultations/2009_pharma/european_patent_office.pdf.

3.2.4. Settlements and Other Agreements

Patent Settlements

The inquiry established that between 2000 and June 2008, more than 200 settlement agreements were concluded between originator and generic companies. They covered some 49 medicines, of which 31 medicines (i.e. 63%) were best-selling medicines that lost exclusivity between 2000 and 2007. The vast majority of the settlements was reached in the context of litigation cases[32], the remaining settlements were concluded in out of court disputes and/or in the framework of opposition proceedings.

In approximately half of the settlements in question the generic company's ability to market its medicine was restricted. A significant proportion of these settlements contained – in addition to the restriction – a value transfer from the originator company to the generic company, either in the form of a direct payment or in the form of a licence, distribution agreement or a "side-deal". Direct payments occurred in more than 20 settlement agreements and the total amount of these direct payments from originator companies to generic companies exceeded € 200 million. The latter type of agreement has attracted antitrust scrutiny in the USA.

Other Agreements

Between 2000 and 2007, originator companies and generic companies entered into a large number of other agreements concerning the sale/distribution of generic medicines. One third of these agreements were concluded with generic companies before the originator company's product lost exclusivity ("early entry agreements"). One cannot exclude that theseagreements could be used to anticipate generic competition or to react to the presence of a generic company. The majority of the early entry agreements contained clauses that provided for a certain type of exclusive relationship between the contracting parties.

Half of the early entry agreements were concluded in the last year before loss of exclusivity. The duration of these agreements exceeded the date of loss of exclusivity on average by more than two years. For most of those agreements, the generic products were the first generic products on the market and, thus, were likely to benefit from certain first mover advantages.

3.2.5. Other Practices Affecting Generic Entry

Apart from originators' medicines obtaining patent protection, all medicines, whether originator or generic, need to obtain a marketing authorisation and in most Member States also pricing and reimbursement status before they can be put on the market. A number of originator companies intervened before marketing authorisation and/or pricing and reimbursement bodies when generic companies applied for marketing authorisation and pricing/reimbursement status for their medicines, claiming that

[32] See section 3.2.2. above. NB: One settlement agreement can relate to more than one litigation case.

generic products were less safe, less effective and/or of inferior quality[33]. Certain originator companies also argued that marketing authorisations and/or obtaining pricing or reimbursement status could violate their patent rights, even though marketing authorisation bodies must not take this argument into account according to EU legislation.

From the litigation reported, the claims of these originator companies were upheld in only 2% of the cases concerning marketing authorisation, suggesting that the arguments submitted by these originator companies in many cases could not be substantiated. Originator companies had also a low success record in cases concerning data exclusivity, i.e. when they claimed that marketing authorisation for a generic product cannot yet be granted due to data exclusivity rules protecting the originator product. The final court judgements confirmed claims of originator companies in 19% of those cases.

Intervention and litigation by originator companies in administrative proceedings for generic medicines can lead to delays to generic market entry. In relation to a sample that was investigated, the inquiry showed that marketing authorisations were granted on average four months later in cases in which an intervention took place. The sector inquiry produced evidence that such practices generated significant additional revenues on a number of originator products.

Originator companies devote a significant part of their budgets to marketing of their products with medical doctors and other health care professionals. The sector inquiry produced indications that some originator companies sought to put into question the quality of generic medicines, as part of a marketing strategy, and even after the generic product was authorised by the relevant authorities and was available on the market.

Finally, there are indications that a number of originator companies attempted to influence wholesalers preparing for the supply of generic products. Also some generic companies complained about interventions at supply sources for the active pharmaceutical ingredients needed to produce the generic medicines in question.

3.2.6. Life Cycle Strategies for Second Generation Products

Incremental research is important as it can lead to significant improvements of existing products, also from the perspective of the patients. Amongst others these may include the discovery of new therapeutic uses for a given product, which may represent important innovations in terms of public health protection, or certain categories of changes to the products formulation within the same indication. Patents protecting the results of incremental research must meet normal patentability requirements of novelty, inventive step, and industrial applicability. In the course of the sector inquiry generic companies and consumer associations sometimes questioned the actual improvement of certain categories of changes, in particular with respect to their therapeutic benefits.

---

[33] 211 cases were reported whereby originator companies made claims regarding generics (sometimes multiple claims). The claims were that the generic products were less safe (75% of the cases), less effective (30% of the cases), inferior (30%) or subject to counterfeit (1.4%).

The findings of the inquiry suggest that for 40% of the medicines in the sample selected for in depth investigation, which had lost exclusivity between 2000 and 2007, originator companies launched second generation or follow-on medicines. Nearly 60% of the patent related litigation cases between originator and generic companies examined in the context of the inquiry concern medicines that moved from first to second generation products.

The launch of a second generation product can be a scenario in which an originator company might want to make use of instruments that delay the market entry of generic products corresponding to the first generation product. The companies have an incentive to do so in order to avoid generic exposure for the second generation product.

In this respect the inquiry indicates that in order to successfully launch a second generation medicine, originator companies undertake intensive marketing efforts with the aim of switching a substantial number of the patients to the new medicine prior to the market entry of a generic version of the first generation product. If they succeed, the probability that generic companies will be able to gain a significant share of the market decreases significantly. If on the other hand generic companies enter the market before the patients are switched, originator companies may have difficulties in convincing doctors to prescribe their second generation product or in obtaining a high price for the second generation product.

On average the launch took place one year and five months before loss of exclusivity of the first generation product. In some cases the first medicine was withdrawn from the market some months after the launch of the second generation medicine.

3.2.7. Cumulative Use of Practices against Generic Companies

Patent and other strategies/instruments described above may sometimes be used cumulatively with a view to prolonging the life cycle of medicines. The extent to which these instruments are used depends on the commercial importance of the medicines. The sector inquiry shows that more life cycle instruments are used for best-selling medicines.

The combined use of life-cycle instruments may increase the likelihood of delays to generic entry. Delays due to the use of several instruments may sometimes be cumulative. More generally, it may significantly increase legal uncertainty to the detriment of generic entry. In this respect it is recalled that any unwarranted delay is not only detrimental to individual companies, but can cause harm to public health budgets and ultimately consumers.

It should be clarified, however, that the use of several instruments that are in themselves legitimate does not necessarily render their combination contrary to competition rules.

A case-specific analysis would be required to establish the precise effects of company behaviour on generic entry. Whilst such an analysis must be left to individual enforcement action where needed, the technical annex to the Final Report provides a number of examples and evidence based on concrete cases pointing towards such effects without specifying that the behaviour in question is contrary to EC competition law.

3.3. Competition between Originator Companies – The Issues

The inquiry also sought to examine whether the behaviour of originator companies might be among the reasons for the difficulties to bring new medicines to the market[34].

3.3.1. Patent Strategies

Originator companies continuously identify the most promising patent strategies in order to protect their assets. This is key for their innovative efforts. In certain cases, however, companies apply patent strategies which may interfere with the development of a competing medicine. When such strategies mainly focus on excluding competitors without pursuing innovative efforts, they are called by some originator companies "defensive patent strategies"[35].

Such "defensive patent strategies" can serve several purposes. First, they create an enforceable right, which may prevent competitors from developing the subject matter of that patent. Secondly, they create prior art as soon as the patent application is published. Thus the development of the published invention may cease to be of commercial interest to other companies as they would not be able to get patent protection for their development.

At the same time some companies disputed these findings and maintained that they engage in patenting activities to obtain legitimate business opportunities, e.g. through licensing. Furthermore, EPO recalled the policy aspect of dissemination of technical information, as third parties remain free to build on the information disclosed in such patent applications.

Originator companies also mentioned the possibilities of competitors to introduce voluntary divisional patent applications as an obstacle to their innovative efforts[36].

3.3.2. Patent-Related Exchanges and Litigation

In total, the inquiry reveals at least 1 100 instances where the patents held by an originator company potentially overlap with the medicines, R&D programmes and/or patents held by another originator company for their medicine[37]. In these cases originator companies might find their research activities blocked, with detrimental effects on the innovation process.

---

34 As indicated above, other factors quoted by the originator industry for the decline in innovation as evidenced by a decline of novel medicines reaching the market include increased scientific complexities, high attrition rates in late stage development due to regulatory risk aversion and uncertainty about the financial rewards. These factors were not subject of the inquiry.

35 As stated above, the term "defensive" patents cannot be found in patent law and all patent applications need to be evaluated on the basis of the statutory patentability criteria, not on the basis of underlying intentions by the applicant. Also it is an inherent feature of a patent system to grant exclusive rights. The notion of "defensive patents" should therefore not be understood to mean that these patents are of a lower quality or value, but it tries to capture a classification made in industry for this type of patents from a commercial perspective.

36 For the efforts of the EPO to limit the possibilities of voluntary divisional patent applications see above footnote 29.

37 These overlaps are based on information provided by responding originator companies identifying such cases.

In many cases originator companies managed to settle potential disputes, for instance through licensing arrangements. However, in approximately 20% of the 99 cases where a licence was requested, the requesting companies did not obtain a licence. Reportedly, in several cases this led to the discontinuation of the R&D project or required additional efforts to go around the obstacles.

Whilst the selection of the 219 molecules was largely based on patent expiries to capture the relationship between originator and generic companies, the inquiry still finds that originator companies engaged in 66 litigation cases against other originator companies. The patent-related litigation concerned 18 medicines. In 64% of the cases, litigation was concluded by means of settlement agreements. The number of cases where a final judgment was reported was relatively low (thirteen of the 66 cases), with patent holders losing ten of the thirteen cases (77%).

3.3.3. Oppositions and Appeals

Between 2000 and 2007, relating to the sample of medicines under investigation, originator companies mainly opposed each other's secondary patents.

The opposing originator companies were very successful when challenging the patents of other originator companies. They prevailed in approximately 70% of final decisions rendered by the EPO (including the Boards of Appeal). In addition, the scope of the patents was reduced in another 19% of the cases.

3.3.4. Settlements and Other Agreements

The inquiry confirmed that originator companies concluded settlement agreements with other originator companies in the EU in order to resolve claims in patent disputes, oppositions or litigation. In the period 2000 – 2007, some 27 settlement agreements relating to the sample under investigation were reported. Approximately 67% of these settlement agreements concerned a licence agreement (including cross licensing).

Besides settlement agreements, the findings of the inquiry also reveal that originator companies concluded other types of agreements with each other. In total, some 1 450 originator-originator agreements were reported. The majority of agreements concerned the commercialisation phase rather than the R&D phase.

81% of the agreements for which the originator companies submitted a combined market share of the contracting parties exceeding 20% contained provisions that provided for some kind of exclusive relationship between the companies, i.e. the agreements provided for an exclusive supply obligation, exclusive sourcing, exclusive licensing or any other kind of exclusivity, and/or a non-compete obligation. The average duration of these agreements with an exclusivity and/or non-compete obligation was eight years.

4. CONCLUSIONS

The sector inquiry has provided the Commission with reliable data on how competition functions in the pharmaceutical sector as regards the competitive relationship between originator and generic companies and amongst originator

companies, quantifying industry practices and pointing to certain areas of concern. The report clarifies in particular how industry operates in the existing legal framework. The acquired knowledge will also benefit all other interested parties in their understanding of the competitive relationships in the sector. A reliable factual basis is indispensable for the Commission to identify specific needs for action and to set priorities. Furthermore, national policy makers and public authorities may decide to take further action based on the analysis, for instance in relation to pricing and reimbursement policies.

Any action by public authorities in the pharmaceutical sector should aim at creating a competitive environment that ensures that Europe's citizens have access to innovative, safe and affordable medicines without undue delays. In this respect both competition law enforcement and regulatory measures can and are to be considered to improve the functioning of the market to the benefit of consumers.

4.1. Intensify Competition Law Scrutiny

Where appropriate, the Commission will make full use of its powers under antitrust rules (Articles 81, 82 and 86 of the EC-Treaty), merger control (Regulation (EC) No 139/2004)[38] and State aid control (Articles 87 and 88 of the EC-Treaty). The Commission, in close cooperation with the National Competition Authorities, will pursue any antitrust infringement in the sector, wherever required by the Community interest. Action can also be taken at national level and in areas which were not the primary focus of the inquiry or are outside its scope.

Market Concentration

As described in the Final Report, the pharmaceutical industry is currently going through a significant phase of consolidation. This includes, on the one hand, an increasing concentration among (large) originator companies as well as the acquisition of biotech companies.

On the other hand, the generic landscape is undergoing substantial changes also, in the form of acquisitions of generic companies by originator companies and through merger & acquisition activities within the generic industry.

The trend towards increased market concentration is followed with attention by the Commission and analysis of these merger cases will benefit from the insights gained through the sector inquiry so as to preserve a competitive structure and process in the market.

Company Practices

Promotion of innovation and driving economic growth are common goals of industrial property law and competition law. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property

[38] Council Regulation (EC) No 139/2004 of 20 January 2004 (OJ L 24, 29.1.2004, p. 1).

rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof[39]. If the existence and exercise of an industrial property right are not of themselves incompatible with competition law, they are not immune from competition law intervention[40]. However, certain practices can only be an infringement in exceptional circumstances[41].

The Commission and national authorities have already taken action in a number of cases in the past for specific violation of competition law in the pharmaceutical sector. The decisions taken include[42]: fines imposed on a pharmaceutical company by the UK competition authority for selling its products to hospitals at very low prices, whilst selling the same products via pharmacies at very high prices to patients, a strategy that could be sustained as doctors were found to be strongly influenced by the brands used in hospitals (NAPP case)[43]; interim measures granted by the French competition authority to a generic company whose products were systematically criticised by a competing originator company's sales staff even after marketing authorisation (Arrow Génériques case)[44]; the decision by the Italian competition authority, in which it was found that the refusal of an originator company to grant a licence for the production of an active ingredient, needed by producers of generic medicines to access national markets where the originator did not have any exclusive rights, constituted an infringement of Article 82 of the Treaty (GSK case)[45]; and fines imposed by the Commission for the abuse of a dominant position consisting in the misuse of regulatory procedures (AstraZeneca case)[46].

The sector inquiry has identified a number of issues that warrant further scrutiny under the competition rules. The Commission in cooperation with the national authorities will not hesitate to make use of its enforcement powers under competition law, where there are indications of practices that have the potential to restrict or distort competition in the market. The Commission also invites market participants who suffer from anticompetitive practices or otherwise have information about such practices to inform the Commission or the relevant national authorities thereof.

---

39 Commission Notice – Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (OJ C 101, 27.4.2004, p. 2).

40 See Commission Notice – Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (OJ C 101, 27.4.2004, p. 2).
See also Judgment of the Court of 27 September 1988, Case 65/86 (Bayer v. Süllhöfer), [1988] ECR, p. 05249.

41 See, for instance: Joined cases C-241/91 P and C-242/91 Radio Telefis Eireann (RTE) and Independents Television Publications (ITP) v Commission (Magill) [1995] ECR I-743, para. 50; case C-418/01 IMS Health v NDC Health [2004] ECR I-5039; case T-201/04 Microsoft v Commission [2007] ECR II-3601, in particular paras. 688 et seq. Commission Communication of 16 July 2008 on an Industrial Property Rights Strategy for Europe - COM(2008) 465.

42 A number of other cases were concluded or are ongoing.

43 See decision of the director general of faire trading No CA98/2/2001 of 30 MARCH 2001, NAPP pharmaceutical holdings and subsidiaries (NAPP), (available at: http://www.oft.gov.uk/shared_oft/ca98_public_register/decisions/napp.pdf).

44 See Judgment of the Cour de Cassation of 13 January 2009, Pourvoi no. P 08-12.510 (press release available at: http://www.conseil-concurrence.fr/user/standard.php?id_rub=211&id_article=865).

45 See Decision of Autorità Garante della Concorrenza e del Mercato of 8 February 2006, No 15175 (Case A363 - Glaxo-PRINCIPI ATTIVI), available at: http://www.agcm.it/.

46 See Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 - AstraZeneca); currently under appeal before the Court of First Instance (T-321/05).

With regard to competition between originator companies in particular, defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked.

As regards competition between originator companies and generic companies, delays to generic market entry are a particular point of concern. The possible use of specific instruments by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way, which may constitute an infringement under Article 81 or 82 of the EC Treaty. In the case of clear indications that a submission by a stakeholder intervening before a marketing authorisation body was primarily made to delay the market entry of a competitor/applicant, injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities.

Agreements that are designed to keep competitors out of the market may also run afoul of EC competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets.

To reduce the risk that settlements are concluded at the expense of consumers, it would seem useful for the Commission to consider further focused monitoring, within the context of the existing legal framework, of those settlements with a potential to adversely affect European consumers. This monitoring would have to take duly into account the administrative burden imposed on stakeholders and will be limited in time until the Commission has gathered sufficient information on the subject matter to decide whether further action is needed.

Any enforcement actions will be initiated on a case-by-case basis and will include a thorough examination of the specifics of each case taking into account the legitimate objectives to protect innovation and the regulatory framework.

Specific enforcement action is already underway in a number of cases. For example, in November 2008 – outside the sector inquiry – the Commission carried out surprise inspections at several companies in different Member States. At the time of the publication of this report no final conclusion was reached.

Other Initiatives

Competition law enforcement by itself will be an important component for the creation of a more pro-competitive environment; however it will not be able to address all main issues identified. Stakeholders made a significant number of comments on the regulatory framework, which they consider decisive for the pharmaceutical sector. The report summarises these comments and proposes possible policy options as to how the regulatory framework should evolve with a view to improving its functioning and minimising the risk of anti-competitive behaviour in the future. The most important areas are patent law, marketing authorisation rules and pricing and reimbursement provisions.

4.2. Rapid Establishment of the Community Patent and Creation of a Unified Litigation System

All stakeholders expressed strong support for the urgent creation of a single Community patent[47] and a unified and specialised patent litigation system[48] in Europe which are currently under discussion. Rulings by the unified litigation system should be swift, of high quality and cost-effective. The results of the inquiry confirm that the Community patent and unified litigation system would create significant cost and efficiency improvements, in particular by reducing the costs associated with multiple filings, by eliminating essentially parallel court cases between the same parties in different Member States and by enhancing legal certainty through the avoidance of conflicting rulings. The Commission continues to make all efforts leading to the rapid adoption of these instruments.

Stakeholders agree on the importance that European - and in the future Community - patents granted by the EPO should respond to a high quality standard. Strong support was further received by all stakeholders that the EPO should be enabled to accelerate procedures whenever possible. Based on its findings of the sector inquiry, the Commission supports the recent initiatives by the EPO to "raise the bar". In this respect the Commission welcomes the recent decision to limit the time period during which the voluntary divisional patent applications can be filed. The Commission also supports the EPO in its efforts to shorten the opposition and appeal procedures.

Regarding the request by the originator industry to introduce so-called "clearing the way" mechanisms to solve patent issues before generic market entry, it is not clear that such new mechanisms would bring a positive added value at this stage when there are still significant discrepancies between national legal systems (e.g. on duration of court proceedings or the conditions/likelihood to obtain interim injunctions). In this light, generic companies should remain able to maintain the first mover advantage in relation to other generic competitors, unless an effective national system to clear the way exists. In any event the conditions, under which such a mechanism could be introduced, would need to be studied carefully.

4.3. Streamlining the Marketing Authorisation Process

The sector inquiry does not include within its scope the in-depth analysis of the Community regulatory framework for pharmaceuticals, which harmonises requirements for the placing on the market of medicinal products with the main objective of protection public health. However, it acknowledges the role played by the regulatory environment as regards the market access of both originator and generic medicines. In the replies to the consultation, various stakeholders have also commented on this legal framework.

---

47 The latest draft text of the proposal for a Council Regulation on the Community patent can be found in Council Working Document 8588/09 of 7 April 2009, at http://register.consilium.europa.eu/pdf/en/09/st08/st08588.en09.pdf.

48 The latest text of the Draft Agreement on the European and Community Patents Court and Draft Statute can be found in Council Working Document 7928/09 of 23 March 2009, at http://register.consilium.europa.eu/pdf/en/09/st07/st07928.en09.pdf.

The Community rules on the authorisation of generic medicines and on data exclusivity were substantially reviewed in 2004, and new provisions apply from 2005, although some will only show their full effects in some years' time.

Overall, most stakeholders called for strict implementation and enforcement of both the old and new regulatory framework. The comments of stakeholders received during the inquiry will constitute an additional valuable information basis to be taken into account by the Commission in the further implementation of its policies in the sector. Moreover, the Commission wishes to make the following observations.

Whilst there is broad consensus amongst stakeholders that – overall – the European framework governing marketing authorisation works well, stakeholders report what they perceive to be shortcomings in implementation that lead to delays and unnecessary administrative burdens for companies.

The Commission will provide full support to the European Medicines Agency (EMEA) and the national agencies to assess how resources and capacity problems may be solved within the network of national authorities and invites Member States to actively contribute to the efforts for speeding up and streamlining administrative procedures to reduce bottlenecks and delays. Moreover, as outlined in the Communication of 10 December 2008 on the future of the pharmaceutical sector, the Commission considers that the network of EU medicines authorities requires optimisation to improve its efficiency, minimise the regulatory burden it generates and thus speed up market access for medicines. The ongoing EMEA review provides a first opportunity for this analysis.

Stakeholders also complained about perceived discrepancies with regard to the national implementation of the EU regulatory framework. Effective enforcement as well as several actions by the Community institutions to remedy this situation are underway such as the implementation of the new Regulation on variations[49] and the ongoing efforts in the network of national marketing authorisation bodies. Where necessary, infringement actions will need to be considered.

The Commission calls upon Member States and national agencies to make better use of the possibility of mutual recognition of marketing authorisations by enhancing procedures and reducing administrative burdens on companies, enabling full mutual recognition without additional requirements imposed on companies. The Commission also underlines the need for stronger coordination between agencies in order to avoid as far as possible discrepancies in the application of the legal framework, making full use of the existing instruments such as the coordination group for mutual recognition established by Directive 2001/83/EC[50] or the various Community databases on medicinal products run by the EMEA. Marketing

---

[49] Changes subsequent to the placing of medicines on the EU market (e.g. change in the production process, change in the packaging, change in the address of the manufacturer etc.) are called 'variations'. Variations to the terms of a marketing authorisation are subject to the requirements of EU law, currently codified in Commission Regulations (EC) No 1084/2003 and (EC) No 1085/2003. From 1 January 2010 Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products will be applicable (OJ L 334, 12.12.2008, p. 7).

[50] Directive 2001/83/EC of 6 November 2001 (OJ L 311, 28.11.2001, p. 67), last amended by Directive 2008/29/EC of 11 March 2008 (OJ L 81, 20.3.2008, p. 51).

authorisation bodies are encouraged to transfer upon request and without delay all information needed by pricing and reimbursement bodies to avoid or at least limit duplication of efforts.

Industry, most prominently generic companies, complained about the possibilities of originator companies to intervene in regulatory proceedings before marketing authorisation bodies and reported about diverging approaches to the disclosure of confidential information taken by different national authorities. The Commission recalls that marketing authorisation procedures are bilateral proceedings between the applicant and the administration[51]. Third party submissions and even less so formal interventions during the assessment of an application for a marketing authorisation are not foreseen in Community pharmaceutical legislation. However given the duty of the competent authorities to consider any information which may impact on the product's assessment (safety, efficacy, quality), marketing authorisation bodies might not be able to simply disregard information submitted by third parties during the marketing authorisation procedure. In this light and irrespective of the reason for which a submission is made, Member States and agencies should ensure that the submission by the third party is well documented, made transparent towards the applicant and should make all necessary efforts that the intervention does not necessarily lead to delays for the applicant. Depending on the national legal framework, companies or health insurers may also pursue damage claims under national legislation in case of proven foregone revenues or savings due to unfounded interventions.

The Commission will continue to strictly enforce the applicable Community law and, for instance, act against patent linkage, as according to Community legislation, marketing authorisation bodies cannot take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines. The Commission is also committed to ensuring that the new data exclusivity rules introduced in Community legislation in 2004 are fully implemented in all Member States.

The Commission equally notes the comments from stakeholders that the data exclusivity framework should be used to improve access to medicines. The Commission is committed to the development of an EU pharmaceutical framework for the 21st century which promotes innovation in particular in areas with unmet medical needs. In its Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector, the Commission announces that it will adopt a report on the use of personalised medicines and '-omics' technologies in pharmaceutical research and development and on the possible need for new Community instruments to support them, by 2010[52]. This report will provide an opportunity to consider the

---

51 Judgment of the Court of First Instance, Case T-326/99 (Olivieri) of 18 December 2003, ECR 2003 p. II-06053.

52 With the emergence of new technologies like pharmacogenomics and patient-specific modelling and disease simulators, personalised medicine is now on the horizon. In the long term, doctors may be able to use genetic information to determine the right medicines, at the right dose and time. This field is already affecting companies' business strategies, the design of clinical trials and the way medicines are prescribed. Although it is too early to say whether '-omics' technologies will indeed revolutionize the sector, the Commission closely monitors the area and will reflect on how it can support its development.

current data exclusivity system, and its ability to contribute to innovation and improve access to medicines.

Companies also call for further international harmonisation in the area of marketing authorisation, mostly between Europe and the United States, to reduce unnecessary regulatory divergences. The Commission fully supports further international harmonisation as this has the potential to considerably reduce the costs of market access and innovation by reducing unnecessary regulatory divergences and points to the strategy for this area outlined in its Communication on a Renewed Vision of the Pharmaceutical Sector of 10 December 2008.

In the course of the sector inquiry generic companies also complained about information campaigns organised by the originator industry questioning the quality of generic medicines. The Commission would like to recall that all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. Any campaigns which put this fact in question ignore the key principles for marketing authorisation in the EU and may mislead the public. The Commission urges Member States to take action, in particular on the basis of Article 97 of Directive 2001/83/EC, if any such campaigns are detected in their territory.

4.4. Improving Pricing and Reimbursement Systems and Developing a Pro-Competitive Environment for Generic Uptake

During the sector inquiry, many stakeholders expressed concerns as regards the delays and uncertainties faced in procedures regarding the pricing and reimbursement status of medicines. Originator companies argued that this would deny patients access to innovative medicines and shorten the period during which the companies enjoy exclusivity. Generic companies argued that such delays limit savings for health bodies.

Key elements of the relevant context for the Commission's strategy in this area are based on the Recommendations of the Pharmaceutical Forum, the Commission Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector and the in-depth monitoring of the functioning of markets in the pharmaceutical sector[53]. Depending on the final outcome of all these initiatives, the Commission will examine the potential need for a review of the existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).

The Commission urges all stakeholders to ensure that the time-limits of three or six months established by the Transparency Directive 89/105/EEC[54] are respected and will continue to investigate all complaints pointing to an incorrect transposition or systematic disrespect of the Directive. The Commission also draws the attention of stakeholders to the possibility to challenge the alleged failure of national authorities

---

53 For details see recommendations of the Pharmaceutical Forum (adopted in October 2008, see http://ec.europa.eu/pharmaforum/), the Commission Communication of 10 December 2008 - COM(2008) 666, 10.12.2008: Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector) and the in-depth monitoring of the functioning of markets in the pharmaceutical sector (as announced in Objective 7 of the above referred Communication).

54 The specific time limits laid down in Directive 89/105/EEC are 90 days for pricing decisions, 90 days for reimbursement decisions or 180 days in case of joint procedures.

to respect the requirements of the Directive before the national courts and encourages affected parties to consider this possibility – including damage claims – when deemed necessary.

The Transparency Directive 89/105/EEC lays down maximum time-limits for pricing and reimbursement decisions, which do not preclude Member States from establishing quicker decision-making procedures where deemed appropriate. In order to speed up pricing and reimbursement decisions for generic products, the Commission invites Member States to consider the introduction of national provisions granting automatic/immediate pricing and reimbursement status to generic products (i.e. without detailed assessment) where the corresponding originator product already benefits from reimbursement based on a higher price. This would considerably alleviate the administrative burden for all concerned and lead to faster access of generic products.

According to generic companies, delays with respect to pricing and reimbursement decisions are sometimes the result of additional requirements, e.g. information on the patent status or an additional evaluation of the bio-equivalence between the originator and the generic product. These additional requirements, requested by the pricing and reimbursement bodies, seem to provide a tool to originator companies to intervene and hence to prolong a given procedure.

The Commission notes that the Transparency Directive requires Member States to set out objective and verifiable criteria for granting pricing and reimbursement status to medicines, so that the competent national authorities must not add criteria or assessments which are not foreseen by national law. It also considers that assessments of the patent status and of bio-equivalence should fall outside the competence of pricing and reimbursement bodies, as they are neither equipped nor competent to deal with these issues. The entry of generics is also affected where authorities in Member States consider that pricing and reimbursement applications constitute a patent violation. In this respect it is underlined that EFPIA, the European association representing originator companies, submitted in the context of the public consultation on the Preliminary Report that applications for marketing authorisations by generic companies would not amount to a violation of patent law. The same logic should apply to applications for pricing and reimbursement status.

In this context, originator companies should not intervene before the pricing and reimbursement authorities in order to raise bioequivalence issues or a potential patent violation by the generic applicant. The Commission considers the pricing and reimbursement procedures as bilateral proceedings between the applicant and the administration. Since the pricing and reimbursement authorities are not competent to assess patent, bioequivalence or safety issues, Member States should disregard third party submissions raising such issues. They should also ensure that interventions by third parties are in general well documented, made transparent towards the applicant and do not lead to delays in processing the price and reimbursement decisions.

Originator companies attribute amongst others part of the delays for originator medicines to cross-border referencing systems used in a number of Member States, and part to the trend towards fragmented decision-making at a more regional/local level. The Commission – whilst fully acknowledging national choices – points to the findings of the sector inquiry that cross-border referencing can lead to delays and

creates sometimes room for misuse (hidden discounts on published price lists used for reference pricing). Regarding the fragmented decision-making, the Commission underlines that this is an issue to be dealt with by Member States.

Stakeholders and in particular originator companies, also complained about the uncertainty of prices/reward when developing new medicines. The duplication of national assessments that try to establish the "added value" of the new medicine over and above existing medicines was specifically mentioned. There is general interest in cross-border collaboration on scientific aspects of added value assessments. In this respect the Commission points to the fact that the duplication of the scientific assessments in the Member States results in additional costs, which are ultimately borne by the consumers/tax payers. Also there is a risk of contradicting decisions on essentially the same questions. Moreover, at this stage smaller Member States do not always have the means for the scientific assessments and thus do not benefit from the possibilities available to larger Member States. Thus a Joint Action on Health Technology Assessment has just been submitted for funding under the Health Programme 2009. In addition, the Commission's proposal on the implementation of patients' rights in cross border healthcare contains a provision for further cooperation on health technology assessment. However cost effectiveness analysis is rather dependent on the budgetary situation and health priorities of each Member State.

Finally, comments were received on national mechanisms that could foster competition forces in the pharmaceutical sector, in particular in the generic sector.

Econometric analysis on the impact of generic entry carried out in the context of the sector inquiry tend to indicate that national regimes with compulsory generic substitution for pharmacists and encouraging doctors to prescribe the substance (as opposed to a particular brand) appear to be favourable to price competition and the level of generic penetration. The same holds for policies involving reimbursement of medicines at the level of the lowest priced product and a frequent adjustment of reimbursement levels to take account of price developments in the market. Likewise, differential co-payment for patients further appears to favour price competition. By contrast, the use of price caps for generic medicines appears not favourable to price competition or generic penetration.

In this light the Commission invites Member States, to the extent not yet done, to consider policies facilitating rapid generic uptake and/or generic competition. Different possible policies to achieve this goal are currently being discussed in the context of the Transparency Committee established by Directive 89/105/EEC.

Certain Member States have achieved significant savings to the benefit of consumers when health insurers carried out tender or similar processes for certain generic products. These systems can help ensure that price reductions offered by generic companies do not stay in the distribution system, but are passed on to consumers. Whilst tenders can be a very powerful tool to reduce costs for public health budgets, the medium and long term effects need also be considered when setting the tender conditions (e.g. duration of award period should not lead to market foreclosure). Compliance with European law (e.g. public procurement law) when carrying out such tenders is also essential.

The Commission will facilitate cooperation between Member States and the exchange of best practices on generic policies in the framework of relevant discussion platforms, such as the Transparency Committee established by Directive 89/105/EEC.

5. THE WAY FORWARD

The sector inquiry confirms that generic entry does not always take place as early as it potentially could under the current relevant legal framework. It shows that company practices are amongst the causes and suggests that a variety of other conditions might play also an important role. The sector inquiry also confirms a decline of novel medicines reaching the market and points to certain company practices that might, amongst other factors, contribute to this phenomenon. Further market monitoring is ongoing trying to identify the additional factors that are likely to play a role in this context.

The Commission will address the issues identified in the course of the sector inquiry by applying increased scrutiny under EC competition law to the sector and by bringing specific cases, where appropriate. First enforcement action is already under way. To reduce the risk that settlements are concluded at the expense of consumers, the Commission will also consider further focused monitoring of settlements that limit generic entry and include a value transfer from an originator company to a generic company.

As far as the regulatory framework is concerned, the Commission reaffirms on the basis of its findings in the context of the sector enquiry the urgent need for the establishment of a Community patent and of a unified specialised patent litigation system in Europe, which pursuant to the sector inquiry has received increased support from the pharmaceutical sector. With respect to patent law the sector inquiry also fully confirmed the relevance of the recent initiatives of the European Patent Office to ensure a high quality standard of patents granted and to accelerate procedures ("raising the bar").

With respect to marketing authorisation the Commission will focus on the full implementation and effective enforcement of the regulatory framework, e.g. regarding patent linkage or the respect of deadlines in the approval procedures. The Commission recalls that third party submissions and even less so formal interventions during the assessment of an application for a marketing authorisation are not foreseen in Community pharmaceutical legislation. It calls upon marketing authorisation bodies to ensure that submissions by third parties that cannot be excluded are well documented and made transparent towards the applicant, and to make all necessary efforts that submissions do not necessarily lead to delays for the applicants.

Concerning pricing and reimbursement the Commission invites Member States to consider (the introduction of) provisions that would grant pricing and reimbursement status to generic products automatically/immediately where the corresponding originator product already benefits from such a status. Moreover, Member States should disregard third party submissions raising patent, bioequivalence or safety issues. Member States should ensure that submissions by a third party at pricing and

reimbursement bodies that cannot be disregarded are well documented, made transparent towards the applicant and should make all necessary efforts that the intervention does not lead to unnecessary delays for the applicant. Finally, the Commission invites Member States to the extent not yet done to consider policies facilitating rapid generic uptake and/or generic competition. It will facilitate cooperation between Member States and the exchange of best practices on generic policies. Depending on the outcome of the various initiatives[55] the Commission will examine the potential need for a review of existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).

Based on the objectives outlined in this Communication, the Commission will continue to pursue a constructive dialogue with all stakeholders to ensure that the innovative potential of the Community's pharmaceutical industry can fully develop and that patients benefit from better access to safe and innovative medicines at affordable prices without undue delays.

[55] Recommendations of the Pharmaceutical Forum, Commission Communication of 10 December 2008 on a Renewed Vision of the Pharmaceutical Sector and the in-depth monitoring of the functioning of markets in the pharmaceutical sector.