



EUROPEAN COMMISSION
Competition DG

Pharmaceutical Sector Inquiry

Preliminary Report

(DG Competition Staff Working Paper)

Executive Summary

28 November 2008

EXECUTIVE SUMMARY

A. Introduction and Overview

The pharmaceutical sector is vital to the health of Europe's citizens. Europe's patients need access to safe, innovative and affordable medicines. The market for prescription and non-prescription medicines is worth over €138 billion ex factory and €214 billion at retail prices. This translates into a retail expenditure of approximately €430 for each EU citizen in 2007.

In January 2008 the European Commission launched a sector inquiry into EU pharmaceuticals markets under the EC competition rules (Articles 81 and 82 of the EC Treaty) because information relating to innovative and generic medicines suggested that competition may be restricted or distorted. This was indicated by a decline in innovation measured by the number of novel medicines reaching the market, and instances of delayed market entry of generic medicines, as compared to what might be expected. This Preliminary Report confirms the decline of new chemical entities reaching the market and the delays of generic market entry and highlights some of the possible causes.

The Preliminary Report does not seek to identify wrongdoing by individual companies or to reach any conclusion as to whether certain practices described in the report infringe EC competition law. It provides the Commission with a factual basis for deciding whether further action is needed.

The inquiry relates to the period 2000 – 2007 and involves investigation of a sample of 219 medicines. The main findings set out in this Preliminary Report relate to:

Competition between Originator Companies and Generic Companies

The preliminary report emphasises that patents are key in the pharmaceutical sector, as they allow companies to recoup their often very considerable investments and to be rewarded for their innovative efforts.

The report also finds that originator companies have designed and implemented strategies (a "tool-box" of instruments) aimed at ensuring continued revenue streams for their medicines. Although there may be other reasons for delays to generic entry, the successful implementation of these strategies may have the effect of delaying or blocking such entry. The strategies observed include filing for up to 1,300 patents EU-wide in relation to a single medicine (so-called "patent clusters"), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding settlement agreements with generic companies which may delay generic entry and intervening in national procedures for the approval of generic medicines. The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer.

The sector inquiry confirms that generic entry in many instances occurs later than could be expected. For a sample of medicines under investigation which had lost exclusivity in 2000 to 2007 the average time to enter after loss of exclusivity was about seven months on a weighted average basis, whereas also for the most valuable medicines it took about four months. On average, price levels for medicines in the sample that faced loss of exclusivity in the period 2000 – 2007 decreased by almost 20% one year after the first generic entry. However, the decreases in price levels were as high as 80-90% in rare cases for some

medicines in some Member States. Based on the sample of medicines under investigation that faced loss of exclusivity in the period 2000 – 2007, representing an aggregate post-expiry expenditure of about € 50 billion over the period (in 17 Member States), the preliminary report estimates that this expenditure would have been about €14 billion higher without generic entry. However, the savings from generic entry could have been about €3 billion more, further reducing expenditure for these medicines by more than 5%, if generic entry had taken place without delay. The findings of the inquiry suggest that the practices under investigation contribute to this.

Competition between Originator Companies

The preliminary findings of the inquiry also suggest that originator companies develop and practise defensive patenting strategies primarily in order to block the development of new competing products. This can lead to obstacles to innovation, in form of higher costs for competing pharmaceutical companies (e.g. for royalties), or in delays.

The Regulatory Framework

In the context of the inquiry stakeholders made a significant number of comments on the regulatory framework, highlighting perceived difficulties and shortcomings. Generic companies and originator companies are in agreement over the need for a single Community patent and the creation of a unified and specialised patent judiciary in Europe. The preliminary findings of the inquiry support these views. Different stakeholders also highlight what they perceive as bottlenecks in the procedures for approval and marketing of medicines (including pricing and reimbursement status), which may contribute to delays in bringing products to market.

B. Market Features of the Pharmaceutical Sector

1. Main Market Features

1.1. Market Structure

The pharmaceutical sector is R&D driven and highly regulated. On the supply side, there are two types of companies. So-called "originator" companies are active in research, development, manufacturing, marketing and supply of innovative medicines. These are usually subject to patent protection, needed to provide a reward for innovation and incentives for future research. When patent protection expires, the originator companies lose their exclusive rights to manufacture and market these medicines and generic manufacturers can enter the market with medicines that are equivalent to the original medicines, but typically at significantly lower prices. This helps contain public health budgets, contributes to an increase in consumer welfare and creates incentives for further innovation.

Originator companies and R&D: During the period 2000 – 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide (approximately 1.5% of turnover was spent on basic research – research to identify potential new medicines, the rest mostly on (pre-)clinical trials and tests). Expenditure on

marketing and promotional activities accounted for 23% of their turnover, thus about one third more than they spent on R&D as a whole. The inquiry confirms that a few "blockbuster" medicines (i.e. where annual global turnover for that medicine exceeds US\$ 1 billion) account for a substantial part of the sales and profits of large originator companies. A number of blockbuster medicines have lost patent protection in recent years and more will do so in the coming years. Combined with other factors, this has given originator companies incentives to extend the period during which they enjoy blockbuster revenues.

Generic companies: Generic companies are in general smaller in size than originator companies and often more regional in nature. Large generic companies are active with a significant range of products. They generate a large part of their turnover from medicines equivalent to blockbuster products whose exclusivity has expired. Their activity in R&D is limited.

Demand for Pharmaceuticals: On the demand side, the pharmaceutical sector is unusual in that for prescription medicines, the ultimate consumer (the patient) is not the decision maker (generally the prescribing doctor and in certain Member States the pharmacist). Nor does the ultimate consumer usually directly bear the costs, as these are generally met by a national health scheme. Because of this unique structure, there is usually limited price sensitivity on the part of decision makers and patients.

1.2. Product Life Cycle

There are three distinct phases to the life cycle of a new medicine: (1) R&D phase up to market launch; (2) the period between launch and loss of exclusivity (e.g. patent expiry); and (3) the period following the loss of exclusivity, when generic companies can enter the market.

During the first phase, companies identify potential new medicines and take them through intensive pre-clinical and clinical trials. The originator companies surveyed rely to a large degree (i.e. for more than one third of all new medicines in the marketing approval phase) on innovations acquired from third parties.

During the second phase, originator companies market the medicines they have developed, with a view to recouping upfront investments and making a profit. Effective patent protection is vital to sustain this business model, which also ensures there are incentives for further innovation.

Following loss of exclusivity, generic medicines can enter the market. The share of generic medicines varies significantly between Member States. In value terms the generic share is the highest in Poland (56%), Portugal and Hungary (both 32%) and lowest in Ireland (13%), France (15%) and Finland (16%).

1.3. Impact of Generic Entry

Of the medicines in the sample that were the subject of further in depth investigation and which had lost exclusivity in the period 2000 – 2007, about half faced generic entry within

the first year after loss of exclusivity (EU average). Measured in value terms, these medicines represent about 74% of sales (sales value in the year of expiry).

The average time gap between the date on which the medicines lost exclusivity and the date of first generic entry was about seven months on a weighted average basis for the sample as a whole, whereas also for the most valuable medicines about four months, with considerable variations across Member States and across medicines.

Generic companies began selling generic medicines on the market at a price that was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, generic medicine prices were on average 40% below the former originator price. The market share (in volume terms) that the generic companies attained was about 30% at the end of the first year and 45% after two years.

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.

Based on the sample of medicines under investigation that faced loss of exclusivity in the period 2000 – 2007, representing an aggregate post-expiry expenditure of about €50 billion over the period (in 17 Member States), the preliminary report estimates that this expenditure would have been about €14 billion higher without generic entry. However, the savings from generic entry could have been about €3 billion more, further reducing expenditure for these medicines by more than 5%, if generic entry had taken place without delay.

2. The Regulatory Framework

Three sets of rules are particularly relevant for the pharmaceutical sector, namely patent rules, marketing authorisation rules and rules on pricing/reimbursement of medicines.

2.1. Patents

In Europe, patent protection can last up to 20 years from the date of a patent application. For the pharmaceutical sector, where the time between filing a patent application and market launch can be significantly longer than in other sectors, supplementary protection certificates (SPCs) can be issued. These extend the effective protection of products already on the market by a maximum of five years.

Despite significant efforts, neither a Community patent nor a Community jurisdiction for patent matters exist. The European Patent Office handles centralised patent applications (and opposition and appeal procedures relating to granted patents). However, once granted, the European patent turns into a bundle of national patent rights, which, in court, must be challenged at national level. This can lead to diverging national decisions and is costly and time-consuming for all stakeholders concerned.

2.2. Marketing Authorisations

In order to maintain public health standards, marketing authorisation procedures verify that medicines are safe, effective and of good quality. Detailed results of (pre-) clinical tests and trials must be submitted for a new medicine. Generic medicines also require marketing authorisations, but applications need not resubmit detailed trial results, if it is shown that the generic product is equivalent to a medicine previously authorised. However abridged applications of this kind are only permitted once the originator company's data relating to the (pre-) clinical tests and trials is no longer protected.

Marketing authorisation procedures are regulated by EU law. There is a centralised application procedure leading to authorisation for the entire EU or national procedures which result in national authorisations that can benefit from mutual recognition in other Member States.

2.3. Pricing and Reimbursement

In almost all Member States the pricing and reimbursement status of a prescription medicine must be determined before launch if funded under the social security system. The underlying objective is to maintain control over national health budgets.

A number of Member States apply policies supporting the sale of generic medicines by combining demand and supply side pricing practices, such as obliging pharmacists to always dispense the cheapest product. In certain Member States health insurers have recently become active in controlling prices for medicines, e.g. through tender procedures.

C. Main Findings

1. Products and Patents

The pharmaceutical sector is one of the main users of the existing patent system. The number of pharmaceutical-related patent applications before the European Patent Office (EPO) nearly doubled between 2000 and 2007. Contrary to what might be assumed, blockbuster medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product. Occasionally they show an even steeper increase at the end of the protection period conferred by the first patent.

2. Competition between Originator and Generic Companies – The Issues

Originator companies use a variety of strategies to extend the commercial life of their medicines for as long as possible.

2.1. Patent Filing and Patent Enforcement Strategies

The preliminary findings of the inquiry are that in recent years originator companies have changed their patent strategies. In particular, originator companies confirm that they aim to develop strategies to extend the breadth and duration of their patent protection.

One commonly applied strategy is filing numerous patents for the same medicine (forming so called "patent clusters" or "patent thickets"). Documents gathered in the course of the inquiry confirm that an important objective of this strategy is to delay or block the market entry of generic medicines. In this respect the inquiry finds that individual blockbuster medicines are protected by up to 1,300 patents and/or pending patent applications EU-wide and that, as mentioned above, certain patent filings occur very late in the life cycle of a medicine.

Patent clusters can lead to uncertainty for generic competitors as to whether and when they can start to develop a generic medicine without infringing one of the many (new) patents, even though patent holders admit internally that some of these patents might not be strong.

A second instrument used by originator companies appears to be filing "divisional patent" applications. Divisional patent applications are instruments allowing the applicant e.g. to split an initial (parent) application. Examination of divisional applications continues even if the parent application is withdrawn or revoked, which can add to the legal uncertainty for generic companies.

Enforcing patent rights in court is generally legitimate: it is a means of ensuring that patents are respected. The inquiry's preliminary finding is however that litigation can be an efficient means of creating obstacles in particular for smaller generic companies. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

2.2. Patent-Related Exchanges and Litigation

Between 2000 and 2007, originator and generic companies engaged, out of court, in at least 1300 patent-related contacts and disputes concerning the launch of generic products. The vast majority of disputes was initiated by the originator companies, which most often invoked their primary patents, e.g. in 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, close to 700 cases of patent litigation between originator companies and generic companies were reported in relation to the medicines investigated. Out of these, 149 cases were reported as litigation in which a final judgment was reached by the court. The duration of patent litigation varied considerably between Member States with an average duration of 2.8 years.

The majority of court cases were initiated by originator companies. However, generic companies won the majority of cases in which a final judgment was given (62%). Unlike during the dispute phase, originator companies primarily invoked secondary patents during litigation.

Litigation was often initiated in many different Member States across the EU 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 225 cases, and were granted such injunctions in 112 cases. The average duration of the interim injunctions granted was 18 months.

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.

2.3. Opposition 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 in the closest available proxy for the pharmaceutical sector than it is in organic chemistry and in all sectors (overall EPO average). Based on the sample investigated, generic companies almost exclusively opposed secondary patents. They prevailed in approximately 75% of final decisions rendered by the EPO (including the Boards of Appeal) during 2000 to 2007, either by achieving the revocation of the patent or by having its scope restricted.

Even though generic companies are very successful in opposing originator company secondary patents, approximately 80% of final decisions took more than two years to obtain. The duration of opposition procedures (including appeal procedures) considerably limits the generic companies' ability to clarify the patent situation of potential generic products in a timely manner.

2.4. Settlements and Other Agreements

The inquiry's preliminary findings confirm that originator companies and generic companies conclude settlement agreements in the EU in order to resolve claims in patent disputes, oppositions or litigation. Between 2000 and June 2008, more than 200 settlement agreements were concluded covering some 49 medicines, of which 63% were best-selling medicines that lost exclusivity between 2000 and 2007.

When assessing the possibilities for settling patent litigation, originator companies are most concerned with the strength of their position, i.e. the probability of winning or losing, as well as with the importance of the product for their overall business (turnover, market shares, presence of other market players, etc.). Generic companies are more concerned with saving costs arising from lengthy and complex litigation proceedings, as well as with removing the uncertainty inherent in patent litigation.

In more than half of the settlements in question the originator company did not impose any restrictions on generic entry. However in 48% of the settlement agreements relating to the EU, the generic company's ability to market its medicine is restricted. A significant proportion of 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.

In the USA, the Federal Trade Commission has scrutinised patent settlements that contained a direct payment made by the originator company to the generic company

combined with a restriction on the generic company to enter the market with its own medicine.

Between 2000 and 2007, originator companies and generic companies entered into a large number of agreements concerning the sale/distribution of generic medicines. One third of these agreements concerned originator medicines which still benefited from exclusivity.

2.5. Other Practices Affecting Generic Entry

The inquiry's preliminary findings confirm that interventions by originator companies before national authorities other than patent offices occurred in a significant number of cases. Originator companies intervened when generic companies applied for marketing authorisation and pricing/reimbursement status for their medicines. Originator companies claimed in their interventions that generic products were less safe, less effective and/or of inferior quality. They also argued that marketing authorisations and/or obtaining pricing or reimbursement status could violate their patent rights, even though marketing authorisation bodies may not take this argument into account. The interventions by originator companies often focused on a few high-turnover products.

When the patent-related matters resulted in litigation, the claims of the originator companies were upheld in only 2% of the cases, suggesting that the arguments submitted against the generic medicine could not be substantiated. Originator companies had also a low success record in cases concerning data exclusivity.

Intervention and litigation by originator companies interfering in administrative proceedings for generic medicines can lead to delays to generic market entry. In relation to a sample that was investigated in depth, it appears that marketing authorisations were granted on average four months later in cases in which an intervention took place. Originator companies believe they have generated significant additional revenues as a result of such practices.

The inquiry's preliminary finding is that originator companies spent on average 23% of their turnover on marketing and promotion activities for their products. As part of their commercial strategies, originator companies do not simply promote their own medicines to doctors and other healthcare professionals. There are also indications of practices seeking to put into question the quality of generic medicines.

Finally, there are indications that originator companies attempt to exercise influence over the distribution channel (wholesalers) and supply sources for the active pharmaceutical ingredients needed to produce the medicines in question.

Direct-to-pharmacy (DTP) distribution is a new trend in the distribution of medicines. In DTP distribution, the pharmaceutical company sells the medicines directly to the pharmacists. According to some stakeholders, this model could eventually lead to less competition at the wholesale level and possibly render it more difficult for smaller originator companies and generic companies to enter the market.

2.6. Life Cycle Strategies for Follow-on Products

The preliminary 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 so called second generation/follow-on medicines. 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. Nearly 60% of the patent related litigation cases between originator and generic companies examined in the context of the inquiry concern the medicines that were subject to switch from first to second generation products.

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 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 have difficulties in convincing doctors to prescribe their second generation product and/or obtain a high price for the second generation product.

The launch of second generation products is often carefully prepared from a patent point of view, in order to ensure that the first generation medicine is adequately protected until the switch takes place. It also requires new patent filings for the second generation product. Whilst it is generally accepted that innovation is often achieved in incremental steps, patents relating to second generation products are sometimes criticised as weak by other stakeholders who argue that they show only a marginal (if any) improvement or additional benefit to the patients.

2.7. Cumulative Use of Practices against Generic Companies

In many instances originator companies use two or more instruments from the "tool-box" in parallel and/or successively in order to prolong the life cycle of their medicines. These instruments notably include secondary patenting, patent related contacts and disputes, litigation, settlements, and interventions before various authorities. Certain originator companies even resorted to the cumulative use of all these instruments for certain 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 and can cost public health budgets and ultimately consumers significant amounts of money.

3. Competition between Originator Companies – The Issues

3.1. Patent Strategies

The preliminary findings of the inquiry show that originator companies engaged in so-called "defensive patent strategies". Patents falling into this category were primarily used in order to block the development of a new competing medicine. The sector inquiry also shows that in such cases the originator companies do not intend to pursue these patents in order to bring a new/improved medicine to the market.

Defensive patenting can serve two purposes. First, it creates an enforceable right, which may prevent competitors from developing the subject matter of that patent. Secondly, it creates 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. Some companies also maintained that they engage in patenting activities to obtain licensing opportunities.

Originator companies also mentioned divisional patent applications as interfering with their R&D projects, which, once granted, they challenged in a number of cases by way of opposition procedures.

3.2. Patent-Related Exchanges and Litigation

In total, the inquiry reveals at least 1,100 instances across EU Member States where the patents held by an originator company relating to a medicine in the sample investigated might overlap with the R&D programme and/or patents held by another originator company for their medicine. This overlap creates significant potential for originator companies to find their research activities blocked, with detrimental effects on the innovation process.

In many cases originator companies tried to settle potential disputes, for instance through licensing. However, in approximately 20% of the cases where a licence was requested the patent holder refused to grant it.

The inquiry finds that originator companies engaged in litigation against other originator companies. The companies reported, in relation to the sample under investigation, for the period 2000 – 2007, a total of 66 cases of patent-related litigation, which concerned 18 different medicines. Litigation was initiated by the patent holder and the originator company allegedly violating the patent in equal proportions. 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 (13 of the 66 cases). The patent holders lost the majority (77%) of cases where final judgments were given.

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. During that period, they prevailed in approximately 89% of final decisions rendered by the EPO (including the Boards of Appeal).

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 preliminary findings of the inquiry also reveal that originator companies concluded many other agreements with each other. In total, some 1,450 originator-originator agreements were reported during the sector inquiry. For certain medicines, a wide range of agreements were reported, of which the majority concerned the commercialisation phase rather than the R&D phase.

D. Comments on the Regulatory Framework

Stakeholders made a significant number of comments on the regulatory framework, which they consider decisive for the pharmaceutical sector. The report summarises these comments without, however, drawing any firm conclusions at this stage.

1. Patents

In their submissions, both generic and originator companies support the creation of a single Community patent to amend the current costly and burdensome system consisting of a bundle of national patents. They also favour the creation of a unified and specialised patent judiciary in Europe replacing the existing fragmented and costly patent litigation system run along national lines.

A significant number of generic companies - and to some extent also originator companies - call upon the EPO to ensure that patents granted are of high quality and to effectively counter patent strategies that may result in unnecessary delays.

The inquiry suggests that significant cost and efficiency improvements could be achieved by creating a Community patent and a unified patent judiciary (e.g. by avoiding the high number of essentially parallel court cases, divergent outcomes of cases and the costs associated with multiple national patents and national patent litigation).

2. Marketing Authorisation

Companies, industry associations and agencies reported bottlenecks in the marketing authorisation procedures, which could lead to obstacles/delays and administrative burdens. The bottlenecks for all companies were allegedly created through the lack of adequate resources in certain agencies. Obstacles for generic companies were said to be created mainly by discrepancies in assessment criteria and by the fact that some regulatory bodies

consider whether the generic product may infringe the originator company's patents (patent linkage) as well as by the disclosure of information to competitors. Patent-linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83.

In particular, certain originator companies would support further international harmonisation of marketing authorisation procedures. Currently there are significant differences between the US and EU markets, e.g. regarding paediatric trials, leading to additional costs and delays. Some efforts are already undertaken in this respect.

3. Pricing and Reimbursement

Originator companies complained in particular about delays and uncertainties created by national pricing and reimbursement procedures. They argued that this would shorten the period during which they enjoy exclusivity and consequently reduce their expected reward. Originator companies attributed the delays and uncertainties amongst others to the fragmentation of the national decision making-process, the increasing use of health technology assessments and the wide-spread use of cross-border reference pricing systems.

Delays are also the main complaint of generic companies. They argue that these delays result not only from the decision making procedures, but often also from the additional requirements for obtaining pricing and reimbursement status for generic medicines, e.g. information on the patent status or concerning complete equivalence between the originator and generic product. These additional requirements seem to give opportunities for originator companies to intervene and hence prolong the de-facto exclusivity period of their product.

Finally, concerns were expressed by originator companies about specific practices to control expenditure, in particular therapeutic reference pricing (and the inclusion of patented products). Generic companies on the other hand would support the wider use of this practice, as it can facilitate market entry for generic products.

E. Launch of Public Consultation

DG Comp is soliciting the views and comments of interested stakeholders about the preliminary findings of the sector inquiry presented in the Preliminary Report. All stakeholders are invited to submit their comments on this report not later than 31 January 2009. All comments should be sent to the following e-mail address: COMP-SECTOR-PHARMA@ec.europa.eu.

The final report of the sector inquiry is expected in the spring of 2009.