

## The Pharma Sector Inquiry

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### Opening of the Inquiry (January 2008)

On 15 January 2008 the European Commission launched an inquiry into competition in the pharmaceuticals sector.

The inquiry is a response to indications that competition in Europe's pharmaceuticals markets may not be working well: fewer new medicines are being brought to market, and the entry of generic medicines sometimes seems to be delayed. The inquiry will therefore look at the reasons for this.

In particular, the inquiry will examine whether agreements between pharmaceutical companies, such as **settlements** in patent disputes, have blocked or lead to delays in market entry. It will also look into whether companies may have created **artificial barriers** to entry (through the **misuse of patent rights, vexatious litigation or other means**). The sector inquiry does not aim to establish infringements of EC competition law by individual companies (Articles 81 and 82 EC).

The inquiry's findings will, if necessary, allow the Commission or national competition authorities to focus any future action on the most serious competition concerns, and to identify remedies to resolve the specific competition problems in individual cases.



*"Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for the money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are being delayed, then we need to find out why, and, if necessary, take action."*

Neelie Kroes, European Commissioner for Competition



EUROPEAN COMMISSION  
Competition DG

**Pharmaceutical Sector Inquiry**

**Preliminary Report**

(DG Competition Staff Working Paper)

28 November 2008

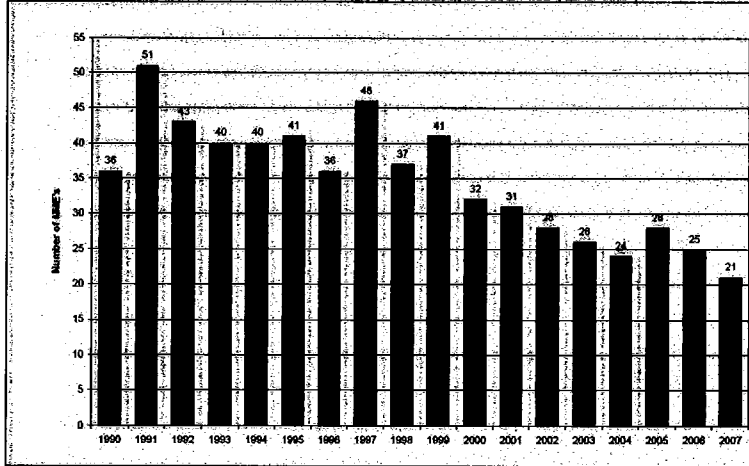
**Preliminary Report**

- The market for prescription and non-prescription medicines is worth over EUR 138 billion ex factory and EUR 214 billion at retail prices. This translated into a retail expenditure of approximately EUR 430 for each EU citizen in 2007.

**Preliminary Report**

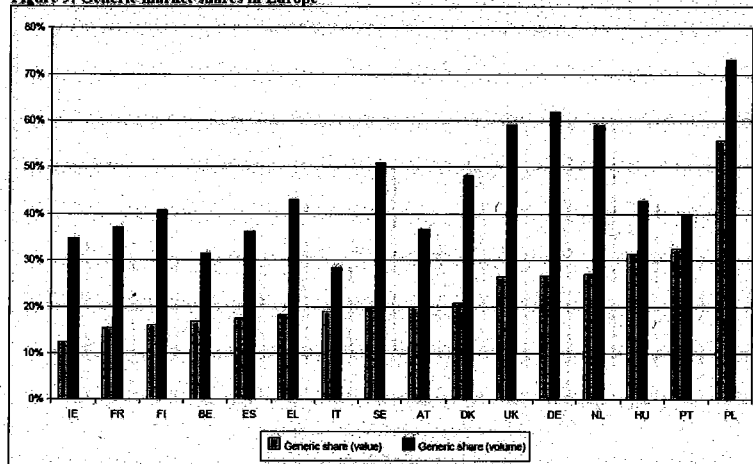
- Patents are key in pharmaceutical sector, as they allow companies to recoup their often very considerable investments and to be rewarded for their innovative efforts.

Figure 8: Number of new molecular entities (NME) first launched worldwide (1990-2007)



Source: EFPIA and CMR International (Thomson Reuter)

Figure 9: Generic market shares in Europe



Source: Pharmaceutical Sector Inquiry (based on IMS data)<sup>51</sup>

## Preliminary Report

- 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.

## Preliminary Report

- The sector inquiry confirms that generic entry in many instances occur later than could be expected.
  - Seven months on a weighted average basis.
  - 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.
  - Decreases in price levels were as high as 80-90% in rare cases.
  - Based on the sample of medicines under investigation that faced loss of exclusivity in the period 200 – 2007, representing an aggregate post-expiry expenditure of about EUR 50 billion over the period (in 17 Member States), the preliminary report estimates that this expenditure would have been about EUR 14 billion higher without generic entry.
- The savings from generic entry could have been about EUR 3 billion more, further reducing expenditure for these medicines by more than 5%, if generic entry had taken place without delay.

## Preliminary Report - 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. Blockbuster medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product.

## Preliminary Report - Main Findings

### 2. Competition between Originator and generic Companies

- Originator companies use a variety of strategies to extend the commercial life of their medicines for as long as possible.
- 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")
- A second instrument used by originator companies appears to be filing "divisional patent" applications
- 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.

### Preliminary Report - Main Findings

- 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 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. 149 cases were reported as litigation in which a final judgment was reached.
- Generic companies won the majority of cases in which a final judgment was given (62%).
- 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.

### Preliminary Report - Main Findings

- 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 EUR 420 million.
- 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.
- Originator companies intervened when generic companies applied for marketing authorization and pricing/reimbursement status for their medicines.
- Intervention and litigation by originator companies interfering in administrative proceedings for generic medicines can lead to delays to generic market entry.

## Preliminary Report – Main Findings

- 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.
- 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.
- Launch of second generation products
- Patents relating to second generation products are sometimes criticized as weak by other stakeholders who argue that they show only a marginal (if any) improvement or additional benefit to the patients.

## Preliminary Report - Public Consultation

- DG Comp solicited the views and comments of interested stakeholders by 31 January 2009.

