

## **Antitrust: shortcomings in pharmaceutical sector require further action**

*Market entry of generic drugs is delayed and there is a decline in the number of novel medicines reaching the market, according to the European Commission's final report on competition in the pharmaceutical sector. The sector inquiry suggests that company practices are among the causes, but does not exclude other factors such as shortcomings in the regulatory framework. As a follow up, the Commission intends to intensify its scrutiny of the pharmaceutical sector under EC antitrust law, including continued monitoring of settlements between originator and generic drug companies. The first antitrust investigations are already under way. The report also calls on Member States to introduce legislation to facilitate the uptake of generic drugs. The report notes near universal support amongst stakeholders for a Community Patent and specialised patent litigation system in Europe.*

Competition Commissioner Neelie Kroes said: "We must have more competition and less red tape in pharmaceuticals. The sector is too important to the health and finances of Europe's citizens and governments to accept anything less than the best. The inquiry has told us what is wrong with the sector, and now it is time to act. When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector."

### **Main findings and policy conclusions**

The inquiry has contributed significantly to the debate on European policy for pharmaceuticals, in particular for generic medicines.

On the basis of a sample of medicines that faced loss of exclusivity in the period 2000 to 2007 in 17 Member States, the inquiry found that citizens waited more than seven months after patent expiry for cheaper generic medicines, costing them 20% in extra spending.

Generic delays matter as generic products are on average 40% cheaper two years after market entry compared to the originator drugs. Competition by generic products thus results in substantially lower prices for consumers. The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible.

The inquiry also confirms a decline of novel medicines reaching the market and points to certain company practices that might contribute to this phenomenon. Further market monitoring is ongoing to identify all the factors that contribute to this decline in innovation.

Reacting to the findings, the Commission will apply increased scrutiny under EC Treaty antitrust law to the sector and bring specific cases where appropriate. The 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. Defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts will remain under scrutiny. To reduce the risk that settlements between originator and generic companies are concluded at the expense of consumers, the Commission undertakes to carry out further focused monitoring of settlements that limit or delay the market entry of generic drugs. 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, injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities.

On regulatory issues the inquiry finds that:

- There is an urgent need for the establishment of a Community patent and a unified specialised patent litigation system in Europe to reduce administrative burdens and uncertainty for companies. A full 30% of patent court cases are conducted in parallel in several Member States, and in 11% of cases national courts reach conflicting judgements.
- Recent initiatives of the European Patent Office (EPO) to ensure a high quality standard of patents granted and to accelerate procedures are welcome. This includes measures taken in March 2009 to limit the possibilities and time periods during which voluntary divisional patent applications can be filed (so called "raising the bar exercise")

The Commission is also urging Member States to:

- ensure that third party submissions do not occur and in any event do not lead to delays for generic approvals
- significantly accelerate approval procedures for generic medicines - for example, the Commission believes that generic products should automatically/immediately receive pricing and reimbursement status where the originator drug already benefits from such status, which would allow for a faster product launch in certain cases
- take action if misleading information campaigns questioning the quality of generic medicines are detected in their territory
- streamline trials that test the added value of novel medicines.

To assist Member States in delivering speedy generic uptake and improved price competition, the report contains an overview of national measures and their effects on generic uptake (volume, prices, number of entrants) and encourages Member States that want to benefit from generic savings to consider such measures. In this light the Commission will also examine existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).

## **Background**

The inquiry began in January 2008 (see [IP/08/49](#) and [MEMO/08/20](#)) to examine the reasons why fewer new medicines were brought to market and why generic entry seemed to be delayed in some cases. The goal is to find ways that help the market work better.

Preliminary results were published in November 2008. More than 70 submissions were received from stakeholders. Consumer associations, health insurers and the generics industry have welcomed the results arguing that they confirm their concerns. The originator industry and their advisors have supported the call for the creation of a Community Patent and a specialised litigation system, whilst arguing that generic delay and the decline in innovation is caused by regulatory shortcomings.

For further information, see also [MEMO/09/321](#)

The final report and more information on the pharmaceutical sector inquiry will be available at:

<http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html>