

Citizens' summary

EU competition inquiry into pharmaceutical sector

WHAT'S THE ISSUE?

In 2008, the EU Commission launched an inquiry to investigate possible **anti-competitive conditions** in the pharmaceutical sector.

The Commission's report presents detailed findings and proposes ways to improve patients' rapid access to **safe, innovative and affordable medicines**.

WHY DOES ACTION HAVE TO BE TAKEN BY THE EU?

Europe's citizens are entitled to safe, innovative and affordable medicines, and the pharmaceutical sector is a vital part of the EU economy. In 2007, the average European spent approximately €430 on medicines – an amount that will continue to increase as the population ages.

The inquiry ties in with other EU initiatives aimed at providing patients with safe, effective and affordable medicines, but also seeks to create a business environment that stimulates research, boosts innovation and promotes a competitive pharmaceutical industry.

WHAT WERE THE MAIN FINDINGS OF THE INQUIRY?

It takes too long for generic medicines to reach the market.

On average, consumers wait 7 months for cheaper generic medicines to become available once patents for brand-name medicines expire. One reason is that drug companies use a variety of techniques to extend the commercial life of their medicines.

When brand-names are forced to compete with generics, prices go down and more patients can be treated. The decreases can be quite substantial. For a sample of medicines we calculated that additional savings of 20% would have been possible if the generic version had become available immediately after the original patent expired.

Fewer innovative medicines are reaching the market.

Certain drug-company practices may contribute to this situation. Monitoring is ongoing to identify all the factors contributing to the decline in innovation.

There is an urgent need for an EU patent and patent-litigation system.

This will cut costs and improve efficiency for citizens and drug companies.

WHAT EXACTLY WILL CHANGE?

The **Commission** will:

- **scrutinise** the sector more closely and where appropriate prosecute specific companies for alleged violation of competition law. First investigations are already ongoing.)
- focus on **enforcing deadlines** for evaluating the safety, quality and efficacy of medicines and granting them pricing and reimbursement status
- help the [European medicines agency](#) and national agencies assess how to solve **resource and capacity problems**.
- examine the need for a **review of EU rules** on pricing and reimbursement

EU countries will be urged to:

- take action against **misleading campaigns** questioning the quality of generic medicine
- introduce mechanisms to significantly **accelerate approval procedures** for generic medicines – such as immediate/automatic pricing
- **streamline trials** that test the added value of medicines
- introduce measures supporting **speedy uptake of generic medicines** and **improved price competition**.

WHO WILL BENEFIT AND HOW?

- **EU citizens** – quicker access to safe, innovative and affordable medicines
- **Producers of generic medicines** – fewer restrictions, a clampdown on misinformation, and faster approval and uptake
- **Producers of brand-name medicines** – if bottlenecks are reduced and procedures are accelerated/streamlined

WHEN WILL THE CHANGES TAKE EFFECT?

Immediately