



Making Medicines Affordable

# EUROPEAN GENERIC MEDICINES ASSOCIATION

## PRESS RELEASE

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Friday, 28 November 2008

### EUROPEAN COMMISSION'S INQUIRY DISCLOSES BARRIERS TO RAPID ACCESS FOR PATIENTS TO AFFORDABLE GENERIC MEDICINES

**DG Competition reports that delaying tactics by originator pharmaceutical companies cost society €3 billion.**

The EGA welcomes the findings of the preliminary report on the sector inquiry, launched today in Brussels. This inquiry was initiated in January 2008 by Neelie Kroes, European Commissioner for Competition, in an attempt to identify inefficiencies in the pharmaceutical market that create obstacles to rapid access for consumers to affordable generic medicines and to new innovative products.

The executive summary of the Commission report states 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 by the European Commission include:

- filing up to 1300 patents across the EU on a single medicine (so-called “patent clusters”),
- engaging in disputes with generic medicines leading to nearly 700 cases of reported patent litigation,
- intervening in national procedures for approval of generic medicines,
- developing follow-on products backed by intensive marketing efforts with the aim of switching patients to the “new” version before the generic product becomes available.

For the sample of 219 molecules that went off patent between 2000-2007, the Commission calculated an average delay after the patent expiry of 4 months for blockbusters and 7 months for all products in general. The report also estimates that during the period 2000-2007 “savings could have been €3 billion higher if generic entry had taken place upon loss of exclusivity expiry.”

Rory O’Riordan, Vice President of EGA on today’s panel points out that in addition “almost half a billion euro were lost over the 7 year period in paying for unnecessary litigation. The report shows that originator brought almost 200 patent disputes a year of which less than 5% were substantiated by the courts.”

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*European Commission Inquiry Discloses Barriers... (continued)*

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Greg Perry, Director General of EGA, responded by reiterating the EGA's longstanding plea for an urgent reform in the pharmaceutical sector that will deal with the loop holes that allow such strategies while opening up the market to authentic generic medicines competition.

Such measures include:

- improving patent quality and patent assessment procedures,
- ensuring all administrative processes for obtaining a marketing authorisation, price and granting reimbursement status for a generic medicines take place before patent expiry,
- developing a pricing and reimbursement structure that preclude switching away from lower priced generic medicines to non added value high priced patented products, and
- implementing market systems which include measures to promote the prescribing, dispensing, and more general use of generic medicines.

“There is still tremendous potential for greater generic uptake in Europe. We at the EGA believe that this preliminary report has identified some key problems in the EU system. We should now be looking for effective ways to improve the sector for patients throughout Europe”, Mr Perry said.