



Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

HAI Europe Statement

DG Competition Pharmaceutical Sector Inquiry- Final Report

10 August 2009- The final report of DG Competition on the [Pharmaceutical Sector Inquiry](#) (8 July 2009) confirms the preliminary findings: not only is the patent system being structurally misused to delay and deter generic competition, but it is also preventing innovation.

The final report has adjusted the harsh tone adopted in the preliminary report in response to the concerns voiced by industry. The pharmaceutical sector has welcomed the new report, stating that it now reflects a more 'holistic' and balanced approach. However, while the tone of the report has been altered, the findings and substantial conclusions have not.

The report maintains the unforgiving conclusions, which are now substantiated with additional supporting data. The report finds that innovator companies systematically use numerous strategies to prolong their market monopoly and deter innovation from competitors, and that such measures are detrimental to national health budgets and access to innovative, safe, and affordable medicines for European consumers.

The report underlines the originator companies' increasing dependence on the revenues from best-selling products, which companies inevitably seek to maintain for as long as possible (p3). To achieve this goal, a so-called 'toolbox of strategies' are used, often in combination, by the industry to discourage, delay, and even prevent generic entry into the market. Strategies include:

- i) Strategic patenting
- ii) Patent litigation
- iii) Patent settlements / reverse settlement agreements
- iv) Interventions by originator companies in decisions by national authorities on marketing authorisation, pricing and reimbursement status
- v) Life Cycle strategies for follow on products (secondary patenting and divisional patent applications)
- vi) Negative information campaigns intended to dissuade consumers from using generic products.

With regard to originator to originator competition, strategies include:

- i) Defensive patent strategies (that "mainly focus on excluding competitors without pursuing innovative efforts")
- ii) Patent litigation and settlement agreements.

The report finds that:

Generics are, on average, 40% cheaper than the originator price two years after entering the market. If generics had entered the market immediately after the originator lost exclusivity, savings in the period of 2000-2007 could have been 20% higher.

One of the main policy recommendations in the report is to create an obligation for pharmacists to dispense the cheapest generic whenever possible, as this will contribute to earlier generic entry and greater savings for national health budgets. The report also supports the rapid establishment of a community patent and unified patent litigation system - a recommendation that also enjoys a broad consensus among stakeholders.

HAI Europe supports the main conclusions and findings of DG Competition's final report. However, we hope that this inquiry and its findings will trigger substantive actions to prevent any anti-competitive behaviour that weakens access to safe, affordable medicines for patients and consumers in Europe.

Link to DG Competition Pharmaceutical Inquiry Index:

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

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