

# DG Competition's Preliminary Report into the Pharma Sector

Brussels, 28 November 2008



DG Competition presented preliminary findings from their inquiry, launched in January 2008, into the pharmaceutical sector in Europe on 28 November.

## Summary

The presentation of facts gathered from the ten month investigation confirmed the fears of many civil society organisations that more affordable generic medicines were being stopped from reaching patients and consumers in Europe. Commissioner Neelie Kroes opened the proceedings with a speech presenting some of the most shocking findings from the inquiry such as evidence that some members of the pharmaceutical industry in Europe “have designed and implemented strategies aimed at blocking or delaying generic entry”. The day continued with a presentation of the findings followed by questions from participants, inputs from several other DGs and substantial participation from industry representatives. However, the overall structure of the programme demonstrated a distinct asymmetry between the commercial and public health perspectives, with significantly less time accorded to discussing the public health consequences of the inquiry's findings.

## The Results

The findings were presented in three sections: *originator to generic competition*, *originator to originator competition*, and *regulatory issues related to the delay of generic entry and a lack of innovation*.

***The primary focus on originator to generic competition*** produced the most comprehensive evidence of harmful practices in the pharmaceutical industry. The findings unveiled a ‘toolbox’ of tactics employed by originator company tactics to discourage, delay, and even prevent generic entry into the market. The ‘toolbox’ included five main practices:

- i. **Patent filing and enforcement: the use of “patent clusters”**, sometimes up to 1300 patents on a single product, create a substantial barrier to potential generic manufacturers
- ii. **Patent related contacts/disputes and litigation** that were overwhelmingly instigated by originator companies and created additional delays for generics
- iii. **Settlements with generic manufacturers that involved value transfers**, including direct payments that often coincided with later entry of the generic
- iv. **Interventions by originator companies in decisions by national authorities** on marketing authorisation, and pricing and reimbursement status; often with misleading claims about inferior quality of generics
- v. **Launching second-generation/follow-on products that “show only a marginal (if any) improvement or additional benefit to the patients”** in order to displace generic medicines based on the original product.

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The report described evidence that these tools were used separately and in conjunction to weaken the ability of generic manufacturers to produce affordable medicines for consumers and patients in Europe. However, the response from the many representatives of originator companies and their lawyers was unapologetic in its tone, reiterating their ‘right’ to protect their investments in any way deemed necessary and with no concern for the impact that this has on the quality of public health and the cost of public health expenditure for EU Member States. At one point in the meeting, one such industry supporter dismissed ‘emotional’ appeals about health as inappropriate to the discussion of patents on medicines and received heavy applause for his efforts.

This dismissal is disturbing, not least for its lack of consideration for the consumer and patient perspective, but also for the fact that it disregards the effect on public health expenditure for Member States. At a time when fiscal discipline has never been more important, promoting practices that artificially inflate the cost of medicines for health care funders is an irresponsible approach. The simple fact is that generic entrance into the pharmaceutical market lowers the cost of medicines for both consumers and governments. It is not simply a matter of emotion, but a matter of economics.

***The second focus of DG Competition’s presentation addressed originator to originator competition***, specifically looking at the use of ‘defensive patents’ to impede innovation from competitor companies. As noted in the executive summary of the report, ‘defensive patenting’ serves more than one purpose for originator brands seeking to hinder competition. By creating an enforceable right, the patent prevents research and development, and further to that, the very existence of this right makes development less commercially attractive in the first place and so, discourages innovation.

However, on this issue, there is an important basic point to be made: that innovation is only worthy of the name if it refers to new medicines that meet real public health needs and not if it is simply an example of a ‘me too’ medicine, designed to promote the health of profit margins rather than the health of patients and consumers. The practice of ‘ever-greening’ or introducing follow-on products with none or barely any additional treatment benefits is just as much of a threat to public health systems. It is likely that, given the scope of the practice uncovered by the inquiry’s findings, some basic research may be impeded but, it is also worth noting that ‘me too’ medicines as well potentially beneficial products are affected.

This point of view was woefully underrepresented throughout the proceedings. The European Consumers’ Organisation (BEUC) was a lone voice on the VIP Panel discussion in bringing to light the problem of ‘me too’ medicines and its detrimental role in diverting resources away from basic research that could lead to new medicines that meet public health needs. The 23% that pharmaceutical companies spend on marketing versus 17% on research and development corroborates the industry’s prioritising of promoting new ‘me too’ medicines instead of developing truly innovative new medicines.

***The third and final focus of the findings was concerned with the regulatory framework*** in which the pharmaceutical industry operates. The report noted three key areas where regulatory reform could be improved: patents, marketing authorisation, and pricing and reimbursement.

The preliminary findings of the report call for a single community patent and a unified patent judiciary, claiming it would speed the process, cut costs and reduce regulatory hindrances. While both generic and originator companies have been keen to identify “bottlenecks”, DG Competition must assess whether these are real barriers or just the result of dutiful implementation of marketing authorisation procedures. Promoting competitiveness by speeding up marketing authorisation should not be at the expense of public health and protection of the safety of European citizens.

The need for regulatory agencies to act as firm gatekeepers of public health should be noted, as well as the need to publicly disclose all data related to the efficacy and safety of medicines, which is of public interest. A first priority should be to ensure that all information on drug safety and effectiveness submitted to regulatory authorities is publicly available, including all pre-market laboratory and clinical data and post-marketing studies. ‘Commercial confidentiality’ is not a legitimate reason to withhold data about medicines.

Greater transparency of pricing, with centralised information available on the prices of medicines throughout the EU is also necessary. Unlike other products, medicine prices have fundamental implications for public health, since they determine access to necessary medical care. Decisions on pricing and reimbursement should remain with individual member states. However, the criteria through which a medicine’s effectiveness is appraised should be harmonised as not all member states require pharmaco-economic evaluations.

Additionally, reimbursement decisions should be fully transparent. Currently, a major barrier to transparency is commercial confidentiality of drug safety, effectiveness, and pricing data. Publicly available data on actual production costs would prevent citizens from being overburdened or denied potentially life-saving treatments by unreasonably high prices.

## Conclusion

Though DG Competition’s inquiry has brought a number of dubious practices to light that have a damaging effect on public health and public health systems, the tone of the proceedings should lead NGOs and independent patient and consumer organisations to be cautious. Presenters from within the Commission were at pains to demonstrate their support for the patent system; so much so that it almost became the catchphrase of the day. There was still an unquestioning acceptance of the validity of discussing the pharmaceutical sector without reference to public health. Though BEUC echoed the views of many NGOs and independent patient and consumer organisations in calling for the transference of pharmaceutical issues from DG Enterprise to DG SANCO, the day was dominated by a narrow commercial view of the pharmaceutical industry.

The chief concern is that the consultation process, which is open until 31 January 2009, will be skewed by that same narrow commercial perspective reflected at the event. It is, therefore, even more crucial that civil society voices are represented in this process and that the strength of the public health viewpoint is effectively conveyed to DG Competition. There are clear consequences for the quality of health and health care costs in Europe in all three areas of the report and a clear responsibility for NGOs and independent patient and consumer organisations to contribute their analysis, comments and recommendations.

*The full Pharmaceutical Sector Inquiry Preliminary Report can be accessed at:*

[http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/preliminary\\_report.pdf](http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf)