

European Commission

Directorate-General for Competition

Antitrust Registry

1049 Bruxelles/Brussel

BELGIQUE/BELGIË

By email to: comp-sector-pharma@ec.europa.eu

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Dear Sirs

We set out below our comments on the Preliminary Report ("PR") of the Sector Inquiry into Pharmaceuticals published by the DG Competition on 28th November, 2008.

1. GlaxoSmithKline ("GSK") fully endorses the comments prepared by EFPIA on the PR and confirms that it has been fully involved in its preparation. As a result, GSK will confine itself only to a few major points, which it wishes to reinforce.
2. Before commenting on the PR, GSK would like to register its concern at the way in which it was presented, both in DG Competition's Press Release and Press Briefing and at the public hearing. Although both the PR and Commissioner Kroes' remarks did accept that the alleged costs due to delays in generics entry were not exclusively caused by the company behaviours reported on, the clear impression was conveyed that the behaviours largely caused these costs. For example, the title of the Press Release was "Preliminary Report ... highlights cost of pharma companies' delaying tactics". Whatever the precise words used in the report were, the media took away the impression that company behaviour was a very significant – indeed perhaps the sole - cause of the extra cost to payors e.g. Bloomberg's headline was "Drug maker delay on generics cost €3 billion EU says". This is wholly misleading as at no point does the PR identify what, if any, delay in generic entry was in fact caused by innovator company behaviour. Indeed, it contains no evidence, as opposed to conjecture, that company behaviours caused delay, far less that they did so wrongfully.
3. Equally, GSK would like to register its concern at remarks made at the public presentation of the PR on 28th November, 2008. Despite various statements that the PR sought only to provide a factual basis for deciding whether further action was needed (see e.g. para 3 of the Executive Summary), both its tone and certain remarks of the Commissioner and other DG Competition officials contradicted this statement e.g.
 - the use of the word "shocking" by Dr Ungerer to describe the PR's contents
 - "[W]hen we put it on paper, what is wrong, what is absolutely to be changed, then the players in the game so to say are already changing their behaviour so I sincerely hope that our clear language is reason for the industry and certain companies to change their attitude already."

Commissioner Kroes. This alleged connection between DG Competition's language and industry action is disingenuous at the least.

4. Turning to the PR itself, the contents can be seriously criticized for the following reasons amongst many others, all of which are elaborated in more detail in the EFPIA document:

- The PR contains many contradictions e.g. implying that delays are caused by the use of the so-called “toolbox” of legitimate commercial practices, particularly for the biggest selling products, when in reality generic companies choose to launch best selling products far more quickly than other types of products.
- The PR failed to seek to quantify the relative effects (if any) on delay in generic entry due to company behaviours and failed to compare them to other elements inherent in the regulatory system. This means that no conclusions whatsoever can be drawn from any theory of harm.
- Many of the statistics set out by the PR illustrate in reality extremely low numbers e.g. 698 litigations – only 149 of which went to a final decision - in relation to 40,000 patents and patent applications over an 8 year period in relation to 219 compounds and up to 27 Member States, is a very small number indeed. Not only is the number of litigations (and particularly of successful litigations) very small in itself, but from these extremely low numbers, the PR seeks to extrapolate industry-wide accusations.
- The PR uses selective quotations from individual company documents (many of which in fact display nothing but sound commercial practice) to attribute allegedly wrongful intentions and behaviours to the innovative industry as a whole.
- Despite the fact that the theory of harm put forward by the PR is based on cost to payors, the PR fails to investigate to any significant degree the market after “loss of exclusivity”. This is despite the fact that it is clear that that part of the market is not operating competitively for the reasons explained by the CRA report commissioned by EFPIA and that the savings available from introducing effective competition in that market are far greater than the alleged cost of delay in generic entry. As Mr Velsel (CEO, UVIT) put it at the public presentation: “The Commission has not addressed the main problem”.
- DG Competition has ignored much of EFPIA's evidence, including the results of the independent reports of CRA Associates, while uncorroborated claims by the generic companies have received attention. For example, although the PR is clearly influenced by generic claims as to the alleged potential harm that may be suffered if an interim injunction is granted, it makes nothing but passing reference to the harm that is suffered by an innovator if no injunction is granted.
- Many questions in the questionnaires were unclear and capable of different interpretations by different companies e.g. questions to gather data on the concept of the date of “loss of exclusivity” (a key issue in the PR), which were capable of various interpretations, and it is therefore unlikely that they will have been answered in the same way by all companies. Similar observations

can be made in relation to questions which referred to “primary” and “secondary” patents. Lack of clarity, such as these examples, draws into question the reliability of important data sets in the PR.

To reiterate, these are only a few of the issues presented by the PR.

In essence, the PR displays a flawed understanding of the innovation system, the patent system and the market. GSK trusts that these flaws will not be evident in the Final Report, which GSK hopes will reflect the undoubted realities of the pharmaceutical sector. GSK also hopes that, in light of the Lisbon Agenda and the final Conclusions and Recommendations of the High Level Pharmaceutical Forum, the Final Report will seek to protect and promote innovation, rather than imitation. This is important to European citizens and patients who benefit from new medicines and vaccines, and to the continued economic competitiveness of the EU.

Yours faithfully
For GlaxoSmithKline Services Unlimited