

**By E-Mail**

European Commission  
DG Competition  
Avenue du Bourget no 1  
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Belgium

Basel, January 30, 2009

**Pharma Sector Inquiry**

Ladies and Gentlemen

Reference is made to the Preliminary Report of the Pharma Sector Inquiry presented on November 28, 2008. The present document is the response of F. Hoffmann-La Roche Ltd (Roche) within the procedure of public consultation opened by DG Competition.

Roche is an innovation-driven global healthcare company headquartered in Basel, Switzerland and with activities in all EU member states. Our aim as a leading healthcare company is to create, develop, produce and market innovative, high-quality solutions for patients' unmet medical needs. By innovation we mean medically differentiated products that lead to a tangible improvement to the health and quality and length of life of our patients. Continuous innovation is only possible realizing very important R&D investments and assuming high risk. Both, investment and risk, have substantially increased for the innovator company due to higher hurdles set by regulatory authorities (mostly on safety) and payers (for differentiation and value). Sustainable success of this business model is dependent on predictable, strong protection of intellectual property and sufficient risk reward to our investors.

Roche has therefore a high interest in a well functioning healthcare and pharmaceutical market in which the sum of all rules and regulations balances well the legitimate interests of all stakeholders. We are prepared to contribute to any discussion and effort that foster the long-term innovation and medical progress to the benefit of the European population.

The Pharma Sector Inquiry has put a considerable burden on Roche so far. Important internal resources had to be mobilized to satisfy the broad and detailed requests of DG Competition. Overall, more than 400 employees have contributed to the answers provided by Roche to the questionnaires. We hope that this enormous effort can once be considered an investment to the future benefit of patients.

At this time we want to express our disappointment and concern that the focus of the Sector Inquiry is exclusively on the time to market entry for generic copies after loss of exclusivity of the original product. The much longer delays that patients suffer to get access to new innovative treatments in the individual member states even after regulatory approval are not made subject of the inquiry. It is difficult to understand why the Inquiry is focusing on potential financial savings leaving aside vital patients' health and survival interests.

DG Competition has presented their Preliminary Report as a compilation of facts, representing the functioning of the pharma sector. It has to be emphasized, however, that these facts are rather a selection of single anecdotes than a comprehensive picture of the reality. The conclusions drawn by DG Competition are based on this anecdotal patchwork and represent free interpretations thereof. At Roche, interpreting the same facts in the light of our profound knowledge of the sector and our Roche business model, we arrive at conclusions that are mostly contrary to the ones of DG Competition:

1. Generics enter the market quickly exploiting the most attractive opportunities (first). The speed of entry is surprising given all the administrative hurdles existing in the individual markets for the entry of any new products. Overall the system offers the possibility to launch a generic product much faster than a new original product. It is driven by commercial logic that high value products and high value markets are moving faster. Also, the ability to enter the market has improved as penetration speed increases over the period.
2. The Pharmaceutical Industry strongly depends on intellectual property protection. It effectively uses the tools and practices offered by the European patent systems. This is common to all high tech industries.
3. The national systems for patent litigation allow generic and originator companies to successfully challenge "weak" patents. The decision whether and when to challenge is in the hands of the challenger. More than 99 % of all patents are never challenged. 62 % of challenges are successful, proof that the system works effectively.
4. Situations stemming from overlapping patents are generally resolved between the parties and end with deblocking-licenses, cross-licenses or abandon. They do not block promising R&D activities or prevent innovation. The fact base shows only one case in which a research project was abandoned because the patent holder did not grant a requested license.

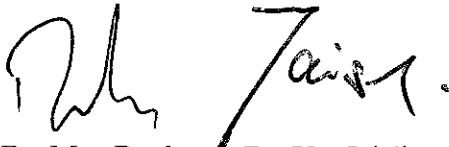
5. A large number of oppositions to pharmaceutical patents occur in practice. This helps ensuring a high quality of patents in the pharmaceutical sector and is an expression of a well functioning system.
6. This highly innovative industry continues its R&D efforts after the launch of a first version of a product. Considering the long timelines for development and registration of product modifications or additional indications companies are working on further improvements of their products up to patent expiry and even beyond.

In order to express a balanced interpretation of the gathered evidence, we invite DG Competition to duly reflect also these equally valid conclusions in the final report. They result from a different perspective taken of the same facts presented in the preliminary report.

Finally, we want to express Roche's full alignment with and support for the observations to the Preliminary Report submitted by the European Federation of Pharmaceutical Industries and Associations EFPIA and the views expressed in their document.

Sincerely,

F. Hoffmann-La Roche Ltd

The image shows two handwritten signatures in black ink. The signature on the left is 'Max Bucher' and the signature on the right is 'Urs Jaisli'. Both are written in a cursive, professional style.

Dr. Max Bucher      Dr. Urs Jaisli