



European Commission  
Directorate-General for Competition  
Antitrust Registry  
1049 Bruxelles/Brussel  
BELGIQUE/BELGIË

**Date: 30.01.2009**

*Preliminary report in the Pharmaceutical Sector Inquiry - reference number 39514*

Ladies and Gentlemen,

The Association of Research-Based Pharmaceutical Manufacturers in Bulgaria (ARPharM) consolidates 24 innovative pharmaceutical manufacturers, operating in the country.

Herewith we would like to declare our full support and agreement to the OBSERVATIONS ON THE PRELIMINARY REPORT IN THE PHARMACEUTICAL SECTOR INQUIRY, submitted by The European Federation of Pharmaceutical Industries and Associations (EFPIA).

The pharmaceutical sector is vital both to the health of the Europeans and to Europe's innovative economy. In this view, one could argue that it should benefit the most from free market and competition principles, laid down in the Communities' Treaties, which the European Commission is called upon to preserve. Nevertheless, this sector is one of the most regulated markets in every aspect possible. While this is done in favour of preserving the safety of the patients and providing the highest level of healthcare possible to the European citizens within the limited resources available, some national regulations can lead to delayed access of medicinal products to the market, thus delayed access of patients to treatment, without meeting any of these goals.

In line with the aforementioned, we would like to share the perspective from the Bulgarian market, which we believe might contribute to the purposes of the Sector Inquiry.

The delay in getting access to reimbursement in Bulgaria, due to the lengthy and complicated process, consisting of 3 separate and independent from each other procedures, takes at least a year following marketing authorisation for generic products and up to 3 years for innovative products.

However, according to the Bulgarian law, the generic pharmaceutical products can apply and receive marketing authorisation at any time prior to expiry of the patent or supplementary protection certificate (SPC) term of the originator's drug. The price approval of the generic drugs also happens before patent and SPC expiration. The current legislation does not stop a generic to apply for access to the reimbursement list within the patent or SPC life of the original, and even to get a positive reimbursement decision, thus allowing for the generic to start to be marketed and reimbursed on the date of the expiry of the protection of the originator.

In view of the above specifics of Bulgarian regulations, no "delaying tactics" of an originator company, even if such exist, can slow down the entry of a generic to the market, leave aside the fact that patent portfolios, patent litigation and settlements, regulation, development and marketing of second generation products, which the Preliminary Report portrays as "shocking facts," and

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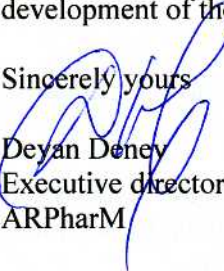
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“inherently suspect conduct”, are legitimate and essential business activities common to all innovative sectors of the economy.

If any delays in market entry exist, they are due only to procedural requirements. We are aware of no anticompetitive activities from patent holders and none such are reported by Bulgarian authorities which negatively affect or slow down generic entry.

We are looking forward to the final report and we strongly believe that it will contribute to further development of the pharmaceutical sector so it can provide what is expected of it.

Sincerely yours

  
Deyan Denev  
Executive director  
ARPharM