

Warsaw, 29 January 2009

**European Commission
Directorate General for Competition**

Ref. No.: 39514

**Comments on the Draft Report on Pharmaceutical Sector Inquiry dated
28.11.2008.
- reply to public consultation**

Polski Związek Pracodawców Przemysłu Farmaceutycznego (the Polish Pharmaceutical Industry Employers Association), an organization of leading generic drugs manufacturers in Poland, has welcomed the report with the hope for the improvement of the existing status quo considerably hindering fair competition in the pharmaceutical market and affecting not only the condition of companies but also the availability of therapies.

This is of particular importance in the EU countries with relatively low expenditure on health care because of a GNP level below the European average.

In Poland, most manufacturers of generic drugs are local level enterprises and only those attaining an annual turnover of approx. Euro 100 M fall into the category of large companies. Even such enterprises stand no chance in the market or legal struggle with global concerns which are capable of spending any money on the protection of their monopolistic positions and use the services of lawyers from internationally renowned law offices (their operations spread also to the media).

The presented report fully confirms our experience.

1. There are marketing companies questioning the legitimacy of generic drugs. We provide examples of such advertisements in App. No. 1. It should be noted that the unfair competition regulations we can refer to are insufficient and the pharmaceutical industry should have special regulations in this respect. In Poland, the Code of Pharmaceutical Marketing Practices is in effect and the companies operating in the market have undertaken to observe it. Regrettably, the decisions of the Ethics Committee are not carried out (see the enclosed letter of [...] in this matter to [...], which is still waiting for a reply).

2. There are attempts at interfering in the drug registration process both informally and legally. Enclosed please find a copy of the letter from the Ministry of Health containing a list of judicial proceedings to award monopolist companies the rights of a party to generic drugs registration procedures, which would give them free access to the registration documentation (App. No. 2).
3. There is a serious problem of “poor” patents (listing in App. No. 3) successfully keeping generic drugs from the market.
4. The consequences of awarding security of claims in the form of a ban on marketing is exemplified by the dispute over [...]. The generic drug marketing was successfully blocked for over 2 years. We estimate that the resulting budget losses were ca EUR 30 M (App. No. 4).

To sum up:

Originator companies conduct a well-thought-out policy of suppressing competition with the support of the huge and unlimited funds they have at their disposal. Any solutions directing both finance and organizational efforts towards research into new medicines instead of preserving monopolies will be beneficial for the market and patient.

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