



Paris, 31 January 2009

Concern: Consultation on the Pharmaceutical sector enquiry - preliminary report

Dear Madam or Sir,

The Medicines in Europe Forum would like to congratulate the Commission on holding this enquiry, which has brought to light unethical behaviours on the part of originator pharmaceutical companies.

The report is detailed, informative and balanced. It shows how originator pharmaceutical companies have abused the patent system in a way that unacceptably delays both generic competition and innovation from other originator companies.

The Medicines in Europe Forum (MiEF) would like to make a few specific comments and recommendations, before making some more general ones.

The enquiry describes how originator companies use different life-cycle management strategies to extend the monopoly on their drugs:

1? *"measures enhancing product loyalty (including criticising competitor's products)" ; "putting into question the efficacy or quality of generic products" :*

the MiEF feels that the situation would only get worse if the Commission's current proposal on patient information (from pharmaceutical companies) is accepted. It's obvious that originator companies would use their new ability to communicate with the public to convince patients to prefer originator drugs. The MiEF therefore urges the Commission to drop this proposal.

2? *"reformulation and second-generation launch" :*

the MiEF would like to emphasise that the Commission can and should act against this useless multiplication of commercial "follow-on" and "me-too products", by requiring pharmaceutical companies to provide information on the added therapeutic value of their new drugs.

3? *"creation of patent clusters (in particular through secondary patents protecting a product)" :*

the Commission can and should act against this "patent evergreening" by stricter enforcement of patent rules regarding novelty and inventivity.

4? *"defensive patenting against other originators" :*

this behaviour is clearly contrary to the public interest and should be prosecuted.

5? *"litigation against originator companies ; litigation against generic companies" :*

this strategy is very costly to patients and to society at large. The Commission should look at ways of speeding up the trials and/or ask for that originator companies pay for the cost to the public when they lose their cases.

6? *"settlements with generic companies" :*

these settlements should be prohibited, and noncompliance should be prosecuted. Originator and generic companies should pay for damages to the public resulting from these settlements.

7? *"interventions at the level of marketing authorities and pricing and reimbursement bodies ; interventions at the level of other stakeholders (e.g. wholesalers and pharmacies)" :*

unfair interventions should be prosecuted.

The above strategies have been rightly considered as anticompetitive by the Commission. But above all they show **an enormous expenditure of energy, misinformation, and money to the detriment of patients and national health insurance systems.**

They show to what extent some pharmaceutical companies have forgotten their obligation to society to bring new medicines, with added therapeutic value, to the market.

It is particularly unacceptable to see that originator companies are fighting each other to delay certain new drug launches. This casts a whole new light on originator companies' stirring speeches about "innovation" and research".

From another perspective, the life-cycle management strategies described in detail in the report come as no surprise. They are taught in every pharmaceutical marketing textbook, and have been used for decades.

And it is plain common sense to realise that originator pharmaceutical companies would do anything to prolong the monopoly on their drugs. It is an illusion to believe that they would stop doing this if they enjoyed prolonged data and/or patent protection, accelerated drug approvals, or European patents.

In conclusion, the Mief encourages the Commission to set up a permanent observatory of marketing strategies, to bring cases of malpractice to court and to take into consideration the specific points (1 to 7) made above.

The MIEF would like to emphasise once again that **the true victims of these condemnable behaviours are not just legal principles or the pharmaceutical generics industry, but the patients** who have to pay too much for drugs, or whose access to drugs is delayed because of anticompetitive practices on the part of originator companies.

The Medicines in Europe Forum requests that the Commission use this enquiry as an opportunity to reconsider its overemphasis on industrial interest when designing pharmaceutical policies, and to reorient policies towards the interests of patients.

Best regards,

Medicines in Europe Forum



Medicines in Europe Forum (MIEF), launched in March 2002, covers most European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. (Contact : pierrechirac@aol.com).