

To
the Honourable
Mr Athanassios Papavassiliou
Chairman of the National Committee of Ethics

Re: Huge delays in the filing of clinical trials

Chalandri, April 9, 2014

Dear Chairman,

As regards your decision for the filing of the initial clinical trials-amendments in the protocol, only upon a telephone appointment with the secretariat of the Committee for the conduct of an administrative inspection of the file, it was verified that the dates set out coincide after three months.

More specifically, in a recent contact established by a company-member of SFEE for the initial filing of a dossier, an appointment was scheduled only for the administrative inspection, on July 7, 2014, with the perspective of approval, *if all went well* in September 2014, knowing that the trial closes the inclusion of patients in October 2014.

Despite the small amount of employees of the National Ethics Committee, the issue of the said 'tragic' delays, both in the filing of the dossiers and in the approval thereof, is now a reason for excluding our company from the conduct of clinical trials, as an insolvent and non-competitive selection. In an era in which the country aims at its growth, the said fact affects the reliability of our country, contributes to the dramatic reduction, even extinction of the clinical trials, increase of unemployment in the research industry and naturally, deprives the country from the influx of substantial resources from abroad.

Apart from the aforementioned extensions of the issue, there are patients who are harmed in this case. Such delays not only exclude them from innovative treatments, but in case they already participate in trials whose amendments are not timely approved, they may endanger even their safety, incurring complications, even of a legal nature, for the National Ethics Committee.

From the Public Administration point of view, we also believe that you cannot deny the receipt of the dossier with such a great delay, which infringes in practice the Directive 2001/20 and the Gov. Gazette 1973/B/31-12-2003.

Finally, you must be aware that by taking delivery of the dossier with the aforementioned delay, the National Ethics Committee contributes in practice to the infringement of the deadline which is provided for, both by the Directive 2001/20 and by the Ministerial Decision ΔΥΓ3/89292/2003 (Gov. Gazette 1973/B/31-12-2003) for the quick closure of the procedure for the conduct of clinical trials. Therefore, you must see to that the appointments are scheduled within a reasonable period of 2-3 days with an official objective manner (e.g. electronic protocol) so as to preserve the activities and competitiveness of our country.

We kindly request for the prompt acceleration of all procedures.

Yours sincerely,

Konstantinos M. Frouzis
President

Yiannis Vlontzos
Vice President

Zefi Vostitsanou
Director of Scientific & Regulatory Issues