Minister for the Interior and Health

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Dear Commissioner John Dalli

As announced in letters of 1 February and 1March 2010 regarding the public consultation paper concerning the functioning of the "Clinical Trials Directive" 2001/20/EC a Danish committee has reviewed the Danish Biomedical Research Ethics Committee System.

./. Enclosed you will find a copy of the report from the committee. The report carefully addresses many aspects of the Danish Research Ethics Committee System and puts forward 40 recommendations to strengthen the committee system. The recommendations are based on the fundamental approach that ethics and research are closely connected, and that quality research must have an ethic dimension integrated in order to succeed.

In chapter 7 of the report you will find the recommendations, while chapter 6 contains the analysis on which the recommendations are based. Among other things the report recommends changes in the organisational structure of the Danish Research Ethics Committee system to ensure more uniformity in the decisions made by the regional Research Ethics Committees. The report also recommends several initiatives regarding quality management and control of research projects.

Furthermore the report recommends that the possibility to conduct research in emergency situations is enhanced (recommendation number 28, page 73 and 107). As mentioned in my letter of 1 March 2010, the issue of emergency clinical trials is much debated in Denmark. In order to give patients the best possible treatment it is essential that there is evidence for the effect of treatments. For some groups of patients this requires that the treatment is tested in emergency situations.

From a Danish point of view it is very important that the issue of conducting clinical trials in emergency situations is addressed on a European level, both in situations where the intervention is presumed to benefit the patient and in the situations where the intervention could benefit the patient group, if not the patient directly. It is my expectation that discussions regarding research in emergency situations could be taken into account when considering the revision of the GCP-directive. The aim should be to improve the possibilities to perform emergency clinical trials involving pharmaceuticals.

One solution could be to accept that the consent from the patient or the patient's legal representative is given *after* the intervention on the condition that the intervention is presumed to benefit the patient. Naturally, such a solution would demand extremely

thorough considerations in the Research Ethics Committee. In these cases it could e.g. be mandatory to receive a medical expert's opinion regarding the trial before approving the application.

Regarding research that may not benefit the patient directly but is presumed to benefit the patient group, the additional protocol to the convention on human rights and biomedicine concerning biomedical research, 2005, from the Council of Europe could be of some inspiration for the European debate. In article 19 (2) regarding research on persons in emergency clinical situations, it is stated that such research can take place provided that the research has "*the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same category or afflicted with the same disease or disorder or having the same condition, and entails only minimal risk and minimal burden.*"

Denmark would welcome a discussion on whether this could be a solution. The respect for the patient must not be compromised, however, if it is in situations where the intervention only entails minimal risk and minimal burden for the patients it might be possible to ensure the interest of both the patients and the research. As well as in situations where the intervention is of directly benefit for the patient as for the situations where it is of benefit for the patient group the Research Ethics Committee must examine the protocols with intensive considerations.

I hope that the Commission will address the issue of emergency clinical trials as soon as possible, and I look forward to the important debate in order to create better possibilities for research in emergency clinical situations for the benefit of both the patients and the development of health research in Europe.

Yours sincerely,

Bertel Haarder