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BEWLGIUM

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REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

I am truly sorry for being late with my comments. During the last weeks I just forgot the schedule of this consultation. My concern is specifically in the emergency trials (Topic 2.6, Consultation item no 16), and I wish to give some views on this topic. I have given a presentation on this topic as the member of EUREC in the EMEA meeting in London some years ago.

The text of the proposal is as follows:

In view of these texts, the Clinical Trials Directive could be amended to the effect that the informed consent and the information from the investigator may take place during or after the clinical trial under the following conditions:

- The trial subject is not in a state to give informed consent;
- The physical or mental conditions that prevents giving informed consent is a necessary characteristic of the research population;
- because of the urgency of the situation, it is impossible to obtain informed consent from the parents/legal representative (in case of adults) in accordance with the Clinical Trials Directive, and it is impossible to give the information, as provided in the Clinical Trials Directive;
- The trial subject has not previously expressed objections known to the investigator.

In this case, the informed consent would have to be obtained as soon as possible from the parents/legal representative (in case of adults) or the trial subject, whichever is sooner. The same holds for the supply of information to the trial subject.
All other rules for clinical trials (approval, safety reporting, etc.) would remain applicable.

There are some issues arising from this proposal. First: In the additional protocol of biomedical research of the Convention of Bioethics there is still one provision: The study shall be approved by an ethics committee as an emergency trial. It is an important provision, while otherwise also in other clinical trials persons that are in the above mentioned conditions could be taken into the research.
Another notice: Most persons that are in a critical conditions, in emergency situations, do not have a legal representative. In our country legal representatives are nominated for a person if he/she is permanently in a situation where he/she cannot anymore govern his/her property. On the other hand we separate this from the capability to give consent to medical care. In the Finnish legislation there is an expression: close relative, otherwise close person or a legal representative, indicating that a family member (spouse, parent or next of kin could serve as the person giving consent in

this case. In the legal view these persons are not legal representatives for an adult, otherwise competent persons.

Medical research in emergency medicine is essential for development of new and better medicines for patients that suffer from serious, life-threatening conditions. It is important that they are not exposed to risks in conditions that can be avoided ie. in trials that can be done in persons that are able to give their own independent and free consent. Often it is not even ethical or fair to ask family members to give an informed consent to a trial when they are afraid of losing their close family member, or ask a person consent when he/she is in pain.

I wish my views could be considered, although they arrive late.

Best regards

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