

UNAUTHORISED TRANSLATION

re: Act amending the act on a biomedical research ethical committee system and treatment of biomedical research projects.

At its third reading on 28 March 2006, Folketinget, the Danish Parliament, passed the amendment to the act on a biomedical research ethics committee system and treatment of biomedical research projects, ref. Act No. 272 of 1 April 2006.

1. Research in emergency situations. The amendment to the act first of all means an extended access to research with medicinal products involving incapacitated trial subjects in emergency treatment situations.

The background for the amendments is that the EC Directive on good clinical practice when implementing clinical trials on medicinal products for human use – Directive - 2001/20/EC - did not provide the opportunity for medicinal product trials without prior consent.

However, the European Commission has announced that it is up to the national authorities to define the concept of "guardian" and thereby define the framework for obtaining a prior surrogate consent.

As research in emergency situations is directed at situations where research is to be implemented immediately in order to have the necessary effect, this required an amendment to the current Danish legislation on trials involving medicinal products, so as to provide a simplified access to obtain surrogate consent in emergency situations.

With the amendment to the act an arrangement has been set up with a "professional legal representative" ("*forsøgsværge*"), so as to enable both the implementation of emergency research involving medicinal products, and the consideration of the trial subject's interests.

The introduction of a "professional legal representative" means that a special entity is established which in these special emergency situations can give prior surrogate consent on behalf of the incapacitated trial subject. The legal representative shall be comprised of an entity of two physicians who may be called in at short notice to evaluate the trial subject's suitability to participate in the relevant trial of medicinal products and to safeguard the trial subject's interests. The two physicians who constitute the legal representative and one of whom must have professional knowledge in the field, must be independent of the trial subject's interests and of any interests in the research project in general.

Clinical trials involving medicinal products on incapacitated trial subjects in emergency situations - just as in general research situations - shall be implemented only where the research project in which the clinical trials are included, has been approved in advance by a research ethics committee and otherwise observes the regulations of Section 13(1) of the Act.

In addition, it is a certain requirement for research in emergency situations that the clinical trials involving medicinal products shall be implemented only if the physical or mental condition of the trial subject, which makes it impossible to obtain informed consent and a usual surrogate consent, is also a necessary precondition for the accomplishment of the research project. Thus it is the physical or mental condition of the trial subject and the urgency of the trial which are decisive of whether the situation is in fact an emergency treatment situation, whereas difficulty in obtaining contact with the closest relatives, the general practitioner, the holder of custody or the guardian shall not allow the application of the regulations under Section 20(a) in stead of the regulations applying to the general surrogate consent.

The specific reasons for involving trial subjects with a health condition which makes them incapacitated to give informed consent shall be stated in the research protocol for the consideration and approval by the research ethics committee.

This regulation is primarily directed to the group of trial subjects who have unexpectedly lost their capacity, typically because of unconsciousness, for instance caused by cardiac arrest, cerebral haemorrhage, clot, poisoning, sudden brain damage or other severe spontaneous injuries or injuries originating from sudden traumas sustained in traffic accidents, falls, etc.

The investigator shall as soon as possible thereafter attempt to obtain informed consent or general surrogate consent (ref. S.17(2)). The subsequent or surrogate consent is to ensure that the information on the project is given to the trial subject or his or her guardian, holder of custody or closest relatives and general practitioner - alternatively the medical officer of health.

2. Weighing out. The amendment to the act also includes the implementation of a regulation from a new EC Directive, Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products. It is also stated in the directive that the consideration of the rights, safety and wellbeing of the trial subject shall prevail over the interests of science and society.

It is assumed that the amendment to the act will not in practice have any appreciable consequences for the function of the committee system as it is assessed that the consideration of the trial subject already prevails over the interests of science and society in the vast majority of the approvals of biomedical research projects given by the committee system.

3. Technical amendments. Other proposed amendments are of a minor radical nature as they are mainly clarifying legal bases and moving regulations to sections of the act where in terms of legal technicalities they logically belong.

4. Commencement. The new regulations shall apply to research projects notified to a research ethics committee after 1 April 2006.

The amendment to the Act is attached for information.

Yours faithfully

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