Clinical trials on medicinal products for human use

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The Committee on the Environment, Public Health and Food Safety adopted the report by Glenis WILLMOTT (S&D, UK) on the proposal for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

The committee recommends that the European Parliament's position at first reading adopted under the ordinary legislative procedure should amend the Commission proposal as follows:

General principle: a clinical trial may be conducted only if : (i) **the rights, safety, physical and mental integrity, dignity and well-being of subjects are protected**, and the ethics

committee has provided assurances thereof; (ii) the data generated in the clinical trial can be expected to be reliable, robust and relevant for improving the prevention and treatment of diseases.

In a clinical trial the safety, rights, health and well-being of subjects should be protected and the data generated should be relevant, reliable and robust and reflect the diversity of the population in terms of age and gender balance. The interests of the participants should always take priority over other interests.

Members insist that it should be ensured that persons assessing the application **do not have conflicts of interest**, are independent of the sponsor, the trial site and the investigators involved, as well as free of any undue influence.

Ethics committee: a clinical trial should be subject to prior authorisation after having been examined by the ethics committee concerned in accordance with the World Medical Association's Declaration of Helsinki.

The Ethics committee shall be an **independent body** in a Member State, consisting of health-care professionals and nonmedical members including at least one well-experienced, knowledgeable patient or patient representative. In cases of clinical trials involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise.

Vulnerable persons: where the subjects belong to vulnerable population groups including pregnant and breastfeeding women, persons deprived of liberty, persons with specific needs including the elderly, frail people and people with dementia, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial.

Low-risk clinical trials: given that low-risk clinical trials have only a very limited and temporary adverse effect, they should be subject to less stringent rules, such as shorter deadlines for approval. Less stringent rules should not compromise scientific standards and should guarantee the safety of subjects at all times. Those low-risk trials should, however, be subject to the vigilance and traceability rules governing normal clinical practice.

For low-risk trials and when marketing authorisation is not the initial objective of the investigator-initiated trial, the cost of the investigational medicinal product should be borne by the national healthcare system.

Assessment report on clinical trials in the field of rare and ultra-rare diseases: in the specific case of clinical trials in the field of rare or ultra-rare diseases, Members propose that the reporting Member State shall seek the expert opinion of the Scientific Advice Working Party of the European Medicines Agency on the disease or group of diseases concerned by the clinical trial in order to help the reporting Member State and the Member States concerned to provide a well informed assessment of the application.

Transparency: Members propose that the assessment report shall be **submitted through the EU portal, and stored in the EU database**. It shall be made publicly available to foster public confidence in the authorisation process.

The subject shall be informed that within one year from the end of the clinical trial or its early termination, the **summary of the results of the trial and a summary presented in terms understandable to a layperson will be made available in the EU database**, irrespective of the trial outcome, or that he or she can obtain information from the investigator or its representative about the overall results of the trial.

The reasons for early termination of a clinical trial shall be published in the EU database.

Members also propose that Member States should impose **fines** on sponsors that do not meet their responsibilities in terms of transparency.

Informed consent: rules on informed consent are established in detail by the Members in order to ensure access to information and to damage compensation.

Informed consentment should be given **freely and voluntarily**. During the prior interview, the potential subject shall also be informed of the right to refuse to participate in the clinical trial without any resulting detriment. The prior interview with the investigator or a member of the investigating team in order to obtain the subject's informed consent shall include a test of full understanding on the part of the subject and/or his or her de facto representative.

Within the original consent, an option of broad consent should be made available to the patient, whereby his/her data could be allowed to be used at the behest of the treating institution for future research.

Specific measures are also applied to clinical trials on pregnant or breastfeeding women, persons deprived of liberty or subjects with specific needs.

Reporting on efficacy defects of authorised investigational medicinal products: efficacy defect on an authorised medicinal product could represent a serious risk for patient safety and should therefore be added as a reporting obligation under this regulation.

Clinical trial master file: although the Commission proposed that the sponsor shall archive the content of the clinical trial master file for at least five years, Members are of the opinion that should a sponsor come under investigation for misconduct, the clinical trial master file would be vital. Therefore the master file should be **archived indefinitely** unless national legislation states otherwise. The master file can be stored in the EU database if necessary.

In order to follow a given clinical trial from initial ethical approval to final publication, Members proposal that a **Universal Trial Registration Number (UTRN)** should be assigned to each trial to be conducted in the Union.