Clinical trials on medicinal products for human use

2012/0192(COD) - 02/04/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 594 votes to 17, with 13 abstentions, a legislative resolution 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.

Parliament adopted its position at first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement negotiated between the European Parliament and the Council. They amend the proposal as follows:

General principle: a clinical trial may be conducted only if: (i) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and (ii) it is designed to generate reliable and robust data.

A clinical trial shall be subject to **scientific and ethical review** and shall be authorised in accordance with this Regulation. The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned.

Simplified procedures: application dossiers for clinical trials should be submitted by means of a single submission portal. In order to avoid administrative delays for starting a clinical trial, the **procedure to be used should be flexible and efficient**, without compromising patient safety or public health.

According to the new text, Member States should **efficiently assess all clinical trials applications within the given timelines**. A rapid yet in-depth assessment is of particular importance for clinical trials concerning **medical conditions which are severely debilitating** and/or life threatening and for which therapeutic options are limited or non-existent, as in the case of rare and ultra-rare diseases.

Vulnerable persons: the assessment of applications for the authorisation of clinical trials should be conducted on the basis of appropriate expertise. Specific expertise should be considered when assessing clinical trials involving subjects in emergency situations, minors, incapacitated subjects, pregnant and breastfeeding women and, where appropriate, other identified specific population groups, such as elderly people or people suffering from rare and ultra rare diseases.

The text underlines that in order to improve treatments available for vulnerable groups such as frail or older people, people suffering from multiple chronic conditions, and people affected by mental health disorders, medicinal products which are likely to be of significant clinical value should be fully and appropriately studied for their effects in these specific groups.

Conditions for the conduct of a clinical trial: the following conditions should be met:

- the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
- the subjects, or where a subject is not able to give informed consent, his or her legally designated representative, have been informed;
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- the rights of the subjects to physical and mental integrity, to privacy and to the protection of the data concerning them are safeguarded;
- the clinical trial has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects and both the risk threshold and the degree of distress are specifically defined in the protocol and constantly monitored;
- the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner;
- the subject or, where the subject is not able to give informed consent, his or her legally designated representative has been provided with the contact details of an entity where further information can be received in case of need;
- no undue influence, including that of a financial nature, is exerted on subjects to participate in the clinical trial.

Informed consent: information given to the subject or his or her legally designated representative shall enable an understanding of:

- the nature, objectives, benefits, implications, risks and inconveniences of the clinical trial;
- the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification;
- the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial; and
- the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical trial is discontinued.

Information should be: (i) be kept **comprehensive, concise, clear, relevant, and understandable** to a layperson; (ii) be provided in a **prior interview** with a member of the investigating team who is appropriately qualified according to the law of the Member State concerned; (iii) include information about the applicable **damage compensation system**.

The sponsor should provide within the time limits a summary of the results of the clinical trial and a summary presented in terms understandable to a layperson and, if appropriate, the clinical trial report.

Subject safety: in addition to serious adverse events and reactions, the new text stipulates that all unexpected events that might materially influence the benefit-risk assessment of the medicinal product or that would lead to changes in the administration of a medicinal product or in overall conduct of a clinical trial are **notified** to the Member States concerned.

Transparency: Members amended the legal text in order to increase transparency, requiring that detailed summaries of the trial be **published on a European database that is accessible to the public**.

Penalties may be imposed in the cases of non-compliance with the provisions laid down in the Regulation on submission of information intended to be made publicly available to the EU database and non-compliance with the provisions on subject safety.