Medicinal products for human use: implementation of good clinical practice in the conduct of clinical trials

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In adopting the report by Mr Amedeo AMADEO (NI, I), the European Parliament called for trials to begin only after the ethics committee had issued a favourable opinion. At the same time, trials on any person incapable of giving informed consent should be banned unless they were of direct benefit to the person concerned. Member States were asked to adopt detailed regulations, if they did not already exist, to protect such persons (e.g. the mentally handicapped or children) against any abuse. It should not be possible for individuals who were incapable of giving their informed consent to participate in clinical trials unless a legally responsible person had consented after clarification of the circumstances. Similarly, if a trial participant was incapable of entering into legal transactions, the informed consent of relatives, the guardian and/or a legal representative was required. Parliament considered that a clinical trial could be undertaken only if: - the right of the participant in the trial to physical and mental integrity was respected, as well as the right to privacy, - the participant in the trial had given his written consent after being informed of the nature, significance and implications of the clinical trial, - an appropriately qualified doctor was responsible for the medical care given to, and medical decisions made on behalf of, subjects. Compensation must be available in the event of injury to or death of a trial participant which was attributable to the clinical trial. If trials had unexpected side-effects, Parliament considered that the sponsor should suspend all recruitment for the study concerned. Substances used in trials must be used in accordance with the principle of good practice, whatever their place of origin. Those responsible for approving 'investigational substances' must possess appropriate training. Parliament called for the outer or immediate packaging of investigational medicinal products to state in, at least, the national languages that the medicinal product was being used for a clinical trial and that it was not for sale.