



*Presidenza del Consiglio dei Ministri*

## **NATIONAL BIOETHICS COMMITTEE**

### **DRUG TRIALS**

(17<sup>th</sup> November 1992)

#### *abstract*

On the one hand, clinical trials on man and animals guarantee drug safety and efficacy, but on the other poses considerable ethical, juridical and scientific problems. The NBC considers that the experimentation on man, if carried out properly and in such a way as not to involve serious risks, is undoubtedly licit. It is even dutiful insofar as it satisfies a principle of solidarity, apart from the therapeutic reasons, considering that information is gathered through research which, even though not having any usefulness for the person undergoing the treatment, becomes part of a common patrimony that anticipates the evolution of the therapy.

Non-therapeutic drug trials require particular caution, such as the approval of the protocol and guidelines by special ethical committees, and should generally be carried out on subjects of a sound mind, and with their prior informed consent. Therapeutic drug trials instead constitute real medical treatment, even though of an experimental type, but however require a strict control of the advantages for the subject undergoing them and must be carried out when their informed consent has been obtained. In the clinical trials of new drugs the procedures of good clinical practice must always be respected, and these must be made known to the researchers and the ethical committees supervising the trials.

With regard to experiments on animals, they must satisfy the criteria set down by international regulations safeguarding every form of life. The alternative models of pharmacological trials represent an opportunity of great interest, but cannot completely substitute the trials on man and animals.

The document highlights the importance of the so-called 'drug-supervision', that is the supervision of drugs before and after going into commerce. During the clinical trial it is in fact useful to have a complete list of all the side effects and establish their prevalence, for which reason every doctor must carry out this type of control very carefully for the common interest.

The Committee recommends the promotion of basic scientific research, stating that many drugs were born from the study of natural processes and not from experiments on animals or man. Furthermore, the opinion denounces the problem of the so-called 'orphan drugs' destined for the treatment of serious pathologies, but which are not developed due to economic reasons. The state and international organizations should therefore draw up incentives so that the pharmaceutical industry, the undisputed protagonist in pharmacological development, invests in less remunerative research sectors too.