



*Presidenza del Consiglio dei Ministri*

## **NATIONAL BIOETHICS COMMITTEE**

### **PHARMACOLOGICAL TRIALS ON WOMEN**

(28<sup>th</sup> of november 2008)

#### *abstract*

Starting with the analysis of the data on clinical experimentation on women, this document shows their under-representation in enrolment and the poor differentiated processing of the results. It shows how the experimentation on women is carried out only for specifically female pathologies (even though there are a number of shortcomings even in this) and is not, on the other hand, carried out for the pathologies which, traditionally male, are increasingly becoming female as a result of the historical-social changes in the female condition. It clearly shows that, although women are the greatest consumers of drugs, the experimentation tends not to sufficiently consider their specific nature and the change in the conditions of women's health, with a consequent increase in side-effects, which are more frequent and more serious with respect to men. The document analyses the main reasons for this shortcoming (at a social, environmental, economic and biological level), discusses the ethical problems arising from it (with particular reference to women of child-bearing age and the question related to the use of contraceptives) and analyses the international and national provisions on the issue.

The Italian Bioethics Committee proposes bioethical lines for an equal consideration of women in experimentation, highlighting the need for a differentiation, showing the dangers of a "neutral" pharmacology, indifferent to sexual differences. Women cannot be assimilated to men, like a mere variable, but have a specificity that experimentation must take into consideration in order to foster medicine that adequately recognises the equal opportunities between men and women.

In order to increase pharmacological experimentation that is differentiated by sex, the Italian Bioethics Committee suggests raising awareness in health authorities and pharmaceutical companies to support separate experimentation for each sex, even though not very profitable, encouraging research programmes on the subject; to promote the participation of women in clinical trials with adequate information on the social importance of the experimentation on women; to guarantee a greater number of women as experimenters and members of ethical committees; to foster healthcare training that pays greater attention to the female dimension in pharmacological experimentation, as well as research and treatment; to increment international as well as national and local cooperation, with special emphasis on the female condition in clinical experimentation.