



Presidenza del Consiglio dei Ministri

ITALIAN NATIONAL BIOETHICS COMMITTEE

FROM PHARMACOGENETICS TO PHARMACOGENOMICS

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abstract

Pharmacogenetics and pharmacogenomics study from a separate and complementary prospective, together they have given access to the genetic basis of drug response, new perceptions in personalising therapies, the creation of drugs focused on a precise genetic target and the production of several of them using not only traditional chemical synthesis, but also cells, tissue and transgenic animals. The NBC has repeatedly dealt with these issues in general and more specifically, however, it recognises the need to discuss them again and give additional in depth consideration to pharmacological therapy.

The first chapter places pharmacogenetics and pharmacogenomics within the process which has transformed genetics into one of the great protagonists of scientific and technological progress. The second chapter is dedicated to drugs, medicines and to pharmaceutical patents. The third chapter goes into the genetic control of drug response. After some clarification of the meaning and use of the terms pharmacogenetics and pharmacogenomics and several historical references, the methods of pharmacogenetical analysis are described in their evolution towards genomics and proteomics. The fourth chapter puts forward strictly bioethical observations. The connection between pharmacogenetics and pharmacogenomics and the impulse given to each of these disciplines by the mapping and sequencing of the human genome are both reaffirmed, along with a reminder that the NBC has already positively judged these developments.

Several indications emerge from the document.

1. In general, there is confirmation of the value of scientific and technological research as an instrument for progress and the moral obligation to guarantee it through adequate support, even in terms of legislation, and human and economic resources.

2. However, the support of state of the art research should not prejudice the improvement of already acquired scientific knowledge, which only awaits transformation into practical application.

3. As regards pharmacogenetics and pharmacogenomics, genetic analysis should be considered one of the essential criteria in the choice of therapy, in cases where there is a definite correlation between genetic constitution and response to a drug.

4. It is recommended that genetic analysis be given major consideration even in terms of pharmacological experimentation as well as medical and epidemiological research in general, so as to consolidate and extend knowledge of this sector.

5. It is emphasised that the patent bestows an excessive burden to the chemical innovation; to the detriment even of the therapeutic benefits (the NBC believes that a thorough examination of this point would be appropriate together with a possible legislative amendment).

6. Lastly, it is pointed out that pharmacogenetics and pharmacogenomics determine a crucial turning point in scientific and technological progress, which, for the first time, offers man the possibility to intervene directly on the project of life.

Consequently, it is of fundamental importance that the scientific world should promote the public's being informed, not only correctly, but also clearly, accessible to everyone. Only in this manner will it be possible to spread the climate of confident reciprocal collaboration that is

essential to obtain the benefits hypothesised from this important chapter in the progress of knowledge.