



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

Opinion

22/CNECV/97

on the

Bill by the European Parliament
and the Council of the European Union

proposing a Directive on

“Medical Devices for *In Vitro* Diagnosis”

The National Council of Ethics for the Life Sciences was requested by Her Excellency the Minister of Health to emit an Opinion on the Bill by the European Parliament and the EU Council proposing a Directive on *Medical Devices for In Vitro Diagnosis*. Wherefore,

1. Considering that:

- 1.1. - the existing Medical Devices for *In Vitro* Diagnosis (**MDID**) are used to carry out analyses of biological samples taken from the human body for the main purpose of obtaining data on physiological and pathological conditions (including congenital anomalies) and of studying histocompatibility among potential recipients of organs or tissues;
- 1.2. - such devices must be reliable (in terms of sensitivity, specificity and reproducibility) and their use must not result in harm to the user and to the person on whom they are applied;
- 1.3. - the Directive proposed by the European Parliament and the EU Council aims at laying down the conditions under which MDID's may obtain the EC Declaration of Conformity, which Declaration is valid as a certificate of quality of such devices when they are placed on the market.



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

2. The National Council of Ethics for the Life Sciences emits the following Opinion:

- 2.1. - The proposed Directive is opportune, for it aims at increasing the reliability of the results (diminishing false negative and false positive results) and also at diminishing the risks incurred by their users.
- 2.2. - It is essential that the tests designed to prove the reliability and safety of the MDID's respect the ethical principles laid out in the relevant international texts.
- 2.3. - As regards the filing for patents on the biological materials used, this Council refers back to its Opinion no.18/CNECV/97 on the Bill by the European Parliament and the EU Council proposing a Directive on the *Juridical Protection of Biotechnological Inventions* (COM (95) 661, Dec.13, 95).
- 2.4. - The proposed Directive provides for the stages from manufacture of the devices to their placement on the market; it is desirable that the recommendations contained therein should conform to the standards laid down by the International Organisation for Standardisation (ISO), and especially with the norms of the ISO Technical Committee (TC) 12, which refer specifically to aspects of internal and external quality control, pre-analysis and post-analysis procedures, reference systems and laboratory safety.
- 2.5. - Since the use of such methods for purposes of self-diagnosis may cause individual decisions or individual behaviour which, in the absence of adequate medical attendance or consultation, might place at risk the health or even the life of the user (e.g. by an interruption of gestation after a pregnancy diagnosis or by suicidal behaviour after a HIV positive diagnosis), it is desirable to safeguard against the use of such devices for non-medical or ethically incorrect purposes.
- 2.6. - The use of MDID's by third parties for purposes that are not strictly medical, by insurance companies or by employers, such as the detection of drug use or HIV positivity or other ends, constitutes reason for serious concern, which the EU Council itself has also expressed.

Lisbon, June 3rd, 1997

Prof. Luís Archer
The President of the
National Council of Ethics for the Life Sciences



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

DECLARATION OF VOTE

I wish to declare, as I have stated already during the debate of this Opinion, that my disagreement was not caused by the draft Opinion submitted by Prof. Lesseps Reys nor by the final text presently approved, but by the fact that, in my view, this request is more technical than ethical in nature, making me wish that this Council would place it in a wider scope, namely that of the ethical questions related to quality of life.

Lisbon, June 3rd, 1997

Prof. Teresa M. Joaquim



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

DECLARATION OF VOTE

Since I consider that the present request for an Opinion contains important matter in terms of aspects that are predominantly technical, and that it is from their application that ethical problems do arise, some of great magnitude, for instance those that refer to the occultation of scientific information, or to the undue utilisation of diagnostic results, or to entrepreneurial ethics - problems which cannot possibly be addressed in the present debate - I vote against this Opinion.

Lisbon, June 3rd, 1997

Dr. Silvério Marques