**NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES**
Presidency of the Council of Ministers

55/CNECV/08

**OPINION Nº 55 OF THE NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES**

# OPINION ON THE DRAFT BILL ON THE LEGAL REGIME OF QUALITY AND SAFETY RELATING TO THE DONATION, PROCUREMENT, TESTING, PROCESSING, PRESERVATION, STORAGE, DISTRIBUTION AND APPLICATION OF TISSUES AND CELLS OF HUMAN ORIGIN

(February, 2008)

The transplantation of organs, tissues and cells is a therapeutic recourse for the treatment of certain human pathologies whose development involves gradual and irreversible functional deterioration, and which cannot be corrected adequately by any alternative means of treatment.

In order to ensure the practice of quality and safety procedures in questions relating to the "donation, procurement, testing, processing, preservation, storage and distribution" of tissues and cells of human origin which are intended to be used for medical purposes, a legislative instrument is proposed which incorporates community directives (Directives 2004/23/CE, 2006/17/CE, 2006/86/CE) on these issues.

Thus, the Draft Bill for the regulation of the "Legal Regime of Quality and Safety Relating to the Donation, Procurement, Testing, Processing, Preservation, Storage, Distribution And Application of Tissues and Cells of Human Origin" was addressed to the CNECV from the Cabinet of the Minister of Health, with a request for the ethical opinion of that body. The draft bill substitutes a preliminary draft of the decree law which was intended to regulate the same matter and upon which the CNECV had already issued its Opinion nº 54/2007.

In that text, which assesses the preliminary draft, within the scope of the Government's legislative competence, the CVECV gave its opinion on the questions of content and form that it considered to require further ponderation, whilst stressing the intrinsic ethical value that may be associated with regulatory measures whose objective is to safeguard the quality of the acts of transplantation that involve organs, tissues and cells, irrespective of their nature and of the way in which the higher, altruistic sentiment of solidarity of the donation of human organs and tissues is expressed.

In Opinion 54/2007, the CNECV expressed its concerns which focussed on three points raised by the preliminary draft of the bill: 1. the scope of the powers of the Authority for Blood and Transplant Services (ASST), which contemplated the regulation of the therapeutic use of tissues and cells of human origin, fundamental, clinical research and the respective financing; 2. the potential conflicts of interest arising from the powers attributed, which might overlap with the powers of other organisations and bodies; 3. the issues arising from the consent of the medical acts practised and which, from the point of view of the CNECV, had not been contemplated fully enough.

In the comparison of the two texts submitted to the opinion of the CNECV (the preliminary draft and the draft bill), some alterations were found to have been introduced, formerly expressed by the CNECV in remarks on format and concerns over content, namely regarding the powers of the ASST. The powers in the area of the technical manipulation and application of reproductive cells and embryonic stem cells produced by artificial reproduction procedures, in the current draft bill, have been attributed coherently to another body (Conselho Nacional da Procriação Medicamente Assistida [*The National Council for Medically Assisted Reproduction*]).

The powers of the ASST itself, identified in Nº 1 of Article 2, paragraph c): "For tissues and cells of human origin, on condition that they include the application in human beings, in the field of clinical tests", have yet to be clarified, which justifies that the reservations stated in Opinion nº 54/2007/CNECV still persist.

The issues concerning consent for the donation of organs and tissues and the respective acceptance also merited equal attention in this draft bill, which is found to contain a more explicit description of the procedures which should be followed in different types of situation.

To sum up, it can be concluded that in its current form the text for the draft bill does not raise any further ethical objections on the part of the CNECV. Furthermore, the CNECV appreciates the fact that the ethical considerations contained in its Opinion 54/2007 were taken into account, where it was sought to better safeguard the values that the control of quality and safety in the clinical use of human tissues and cells and the respective regulation should express.

Lisbon, 12th February, 2008

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*This Opinion was related by the Council members Jorge Soares and Rita Amaral Cabral.*

*This opinion was approved at the plenary session on the 11th December, 2007, at which the following were present:Paula Martinho da Silva, António Vaz Carneiro, Daniel Serrão, Fernando Regateiro, João Lobo Antunes, Jorge Biscaia, Jorge Soares, Jorge Sequeiros, José de Oliveira Ascensão, José Pedro Ramos Ascensão, Maria do Céu Patrão Neves, Fernanda Henriques, Marta Mendonça, Michel Renaud, Miguel Oliveira da Silva, Pedro Nunes, Rui Nunes and Salvador Massano Cardoso.*