



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

ADDENDUM
to
Opinion 22/CNECV/97
on the
Bill by the European Parliament and the Council
proposing a Directive on Medical Devices for *In Vitro* Diagnosis

The request for additional clarification asked of the National Council of Ethics for the Life Sciences (CNECV) by Her Excellency the Minister of Health on the 14th of July, 1997, regarding the matter referred in the title, has the purpose of elucidating whether the ethical principles that guide the procurement and transplantation of organs and tissues, applicable to those acts whose end is the donation or procurement of tissues or organs of human origin for therapeutic purposes - namely, the gratuity of their donation and the prohibition of their commercialisation, informing the donor and obtaining his/her consent - are to be considered as valid for the harvesting of human cells or tissues for the purposes of the preparation of medical devices for *in vitro* diagnosis.

This question is justified by the argument that, should those principles be upheld, difficulties may eventually arise in obtaining the human tissues and cells that are necessary to the production of such devices.

The CNECV is of the opinion that, notwithstanding the eventual risk of the aforementioned difficulties arising, there are no well grounded reasons of an ethical nature that justify the alteration of its Opinion, as previously formulated, concerning the harvesting of cells, tissues or organs for therapeutic purposes - namely, the principles laid down in its Opinion 1/CNE/91,¹ which are considered as reproduced herein, *mutatis mutandis*, for those situations in which the harvesting of such biological products should be destined to the preparation of devices for the purpose of *in vitro* diagnosis.

Lisbon, October 7th, 1997

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for the Life Sciences

¹ Cf. Opinion 1/CNE/91 on the Transplantation of Tissues and Organs, *in Documentation, Vol I* (1991-1993), CNECV, pp. 59-64 (especially points 4.e) and 5.2.d), as well as the 3rd Report on the State of Application of the New Technologies to Human Life, *in Documentation, Vol. III* (1995-1996), CNECV, pp.171-194, (especially p.188).