NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

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OPINION ON THE QUALITY AND SAFETY LEGAL FRAMEWORK FOR THE DONATION, PROCUREMENT, TESTING, PROCESSING, PRESERVATION, STORAGE, DISTRIBUTION AND APPLICATION OF ORGANS OF HUMAN ORIGIN

(September 2012)

CNECV

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I - INTRODUCTION

His Excellency the Deputy Secretary of State to the Minister of Health sent the National Council of Ethics for the Life Sciences (CNECV) a request for an urgent hearing and Opinion on the Draft Bill for the establishment of 'standards to ensure the quality and safety of organs of human origin intended for transplantation to the human body, in order to ensure a high level of human health protection', thus transposing into national law Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010[1] on standards of quality and safety of organs intended for transplantation – hereinafter briefly referred to as Bill.

Because it is a Draft Bill that embodies the transposition of a Directive of the European Parliament and of the Council and ensures the appointment of competent authorities to enforce its content, and also taking into account the reflection already rendered by the CNECV in previous Opinions, it could be said that no immediate ethical objections arise from this document.

In any case, a reading and analysis of the statute justify some considerations on this matter.

Indeed, in recent decades, organ transplantation has gained increasing importance as a therapeutic method and in some circumstances the only recourse available to save or prolong the patient's life.

On the other hand, the transplantation process that includes the donation, procurement, characterisation, testing, preservation, transportation and transplantation of the organ often transcends borders. The frequently low organ availability and medical emergency that dominate this area call for solidarity and international cooperation, making it possible to increase the number and quality of organs available and ensuring better compatibility and quality of the transplant. When facing the strengthening of exchanges between countries with different rules and jurisdictions, there is a need to standardise technical procedures and ensure the quality and safety of both the organs and the acts performed, ultimately to minimize the risks associated with transplantation, avoid the transmission of known diseases and contribute to the promotion of safety, both for donors and recipients.

[1] Official Journal of the European Union: OJ L 207, 6.8.2010, p. 14, with the rectification in OJ L 243, 16.9.2010.

II – GENERAL FRAMEWORK

The CNECV had the opportunity to issue Opinions on previous occasions, in particular with regard to the ethical issues raised by the examination of former regulatory statutes of the transplant activity, to whose general considerations it refers**, namely:**Opinion 1/CNECV/93 – Opinion on tissue and organ transplantation; 41/CNECV/2003 – Opinion on the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin; and 50/CNECV/2006 – Opinion on Draft Bill no. 65/X – Amendment to Law no. 12/93 of 22 April – Procurement and Transplantation of organs and tissues of human origin. Specifically in terms of issues related to the 'donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells of human origin', and 'traceability, notification of serious adverse events and reactions and technical requirements for the coding, processing, preservation, storage and distribution of tissues and cells of human origin', the Council issued its judgment at the appropriate time, in particular through Opinions 54/CNECV/2007 and 55/CNECV/2008.

When establishing an ethical and legal framework on the issue of transplantation, it is important to mention the Convention on Human Rights and Biomedicine (Council of Europe), ratified by Portugal on 3 January 2011 and in force in national legislation since 1 December 2001, and the Additional Protocol to the Convention on Human Rights and Biomedicine signed by Portugal with regard to the transplantation of organs and tissues of human origin; the Charter of Fundamental Rights of the European Union, in particular its article 3[2]; and the UNESCO Universal Declaration on Bioethics and Human Rights[3]. Also worth mentioning are the 'WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation' of the World Health Organisation, whose original version of 1991 was updated in 2010 with a view to incorporating new trends with regard to transplantation, in particular the growing use of tissues and cells of human origin[4].Both the Explanatory Statement and the articles of the Bill in question omit any reference to the documents mentioned, in particular the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of

[2] OJ C 83 of 30.3.2010, p. 389 et seq.
[3] Adopted on 19 October 2005 by the 33rd session of the UNESCO General Conference.
[4] Version approved by the 63rd World Health Assembly of 21 May 2010 – Resolution WHA63.22 – available at http://www.who.int/transplantation/en/.

human origin. Due to their relevance, it is suggested that these references are included in the Bill under consideration.

At the level of the national legal system, the following are to be highlighted:

- Law no. 12/2009 of 26 March, which establishes the legal regime of quality and safety for the donation, procurement, testing, processing, preservation, storage, distribution and application of tissues and cells of human origin, transposing to national law Directives 2004/23/EC of the European Parliament and of the Council of 31 March, 2006/17/EC of the Commission of 8 February, and 2006/86/EC of the Commission of 24 October;

- Law no. 22/2007 of 29 June, partially transposing into national law Directive 2004/23/EC of the European Parliament and of the Council of 31 March amending Law no. 12/93 of 22 April on procurement and transplantation of organs and tissues of human origin;

- Decree-Law no. 244/94 of 26 September, governing the National Register of Non-Donors (RENNDA);

- Order no. 802/2010 of 23 August, creating the National Cross-matching Renal Donation Programme (PNDRC) for the registration of kidney donor-recipient pairs and their cross allocation;

- and Order no. 357/2008 of 9 May, which regulates the national network coordinating procurement and transplantation.

In view of the considerations previously made about this issue, the response to the request made to CNECV will focus on the ethical issues that are limited to the assessment of the mentioned Bill.

III – ANALYSIS OF THE DRAFT BILL

According to the Explanatory Statement of the Bill, 'transplantation involves risks. The extensive therapeutic use of organs for transplantation requires that the quality and safety of these organs is ensured so as to minimise any risk of disease transmission'. Thus, the need to ensure that the organs of human origin intended for transplantation meet the quality and safety criteria common to all the

Member States is justified, in an effort to standardise that reflects at the outset the reality of this ever increasing exchange of organs, tissues and cells of human origin at international level.

The ethical framework in this matter is based on the fundamental values of respect for the autonomy and integrity of the individual, including the need for consent, even if presumed in accordance with already established terms, and also on values of solidarity and altruism.

In turn, the safety and quality of the transplant procedure are also ethical benchmarks to take into account. Such value is reflected in the importance of maximising the success of the technique with minimal risk to the health of both the donor and the recipient, in particular due to the prevention of contamination or deterioration of the organs to be transplanted. Recognising, however, that the risks associated with the procedures cannot be completely eliminated, the assessment of risks and their impact must be ensured *in casu*, along with an accurate and detailed record of all relevant information. This includes the need for follow-up of living donors and recipients, monitoring and managing adverse reactions and acting accordingly, both nationally and in the cases of organ exchange with third countries.

Concrete comment on the draft bill

Article 3 (Definitions)

Several definitions in the aforementioned Directive are transposed; given that Law no. 12/93 of 22 April, amended and republished by Law no. 22/2007 of 29 June already contains in its article 1a the definitions of ‘Organ’, ‘Donor’, ‘Donation’ and ‘Procurement’, even taking into account the specificity of the matter to be transposed, it is suggested, where possible, to harmonise the wording of the concepts taken up again in the bill.

Article 4 (Applicable principles)

Gratuitousness – One of the most pressing ethical issues in transplantation of human biological products, especially those from living donor, concerns the issue of commercialisation of human organs for transplant purposes. The international ethical discussion on the status of the human body, and even

the disparity between legal regulations, makes some countries vulnerable to considering the sale of organs for transplant acceptable and involves the risk of accentuating inequalities and injustices in accordance with the income of its citizens.

Article 4 of the Bill under consideration reinforces the understanding that organ donation by living donors or *post-mortem* – in which one should also avoid, as far as possible, the emotional duress, particularly among family members or friends – must be free and voluntary, which respects the dignity of the individual and strengthens the principle of non-exploitation – or respect for the corpse – undermined by the possibility of commercialisation of the body, or parts of the human body. It safeguards the possibility of coercion in respect of more vulnerable persons or populations and prevents the subversion of the values of altruism and solidarity underlying the act of donation for the possibility of violation of personal integrity in the name of a reward or profit.

This does not preclude the possibility of compensation to the donor for damages and costs resulting from the donation; this compensation may not represent, under any circumstances, a financial benefit or incentive for potential donors. Such compensations should take place transparently and according to regularly auditable procedures.

This understanding is consistent with what is advocated by the major international legal and ethical documents and is already translated in article 9 of the republication of Law no. 12/93, under 'Right to assistance and compensation', which is valued positively.

Chapter III - Competent authority

It is the prerogative of the Member States to designate one or more competent authorities for the functions they are charged with by virtue of the Directive to be transposed. Under the Efficiency Commitment, the 19th Constitutional Government laid down the lines of the Reduction Plan and Improvement of Central Administration (PREMAC), whose implementation began in December 2011. Thereafter, pursuant to article 10(b) of Regulatory Decree No. 14/2012 of 26 January, the *Direção-Geral da Saúde (DGS)* – Directorate-General of Health – succeeded the former *Autoridade para os Serviços de Sangue e da Transplantação* – Authority of Blood and Transplantation Services – in the field of quality, safety and authorisation of units, services and processes for the donation, procurement, testing, processing, preservation, storage and distribution of human blood, blood components, organs,

tissues and cells of human origin. The merger of the *Autoridade para os Serviços de Sangue e da Transplantação* and the *Instituto Português do Sangue* – Portuguese Blood Institute – resulted in the *Instituto Português do Sangue e da Transplantação (IPST, IP)* – Portuguese Institute of Blood and Transplantation – that, in accordance with article 12(a) of Decree-Law no. 39/2012 of 16 February succeeded that authority in the part not taken on by the DGS.

In these terms, the DGS is, in the Bill, taken as the competent authority for the verification of compliance with the requirements of the law in national territory, in conjunction with the *Inspeção-Geral das Atividades em Saúde (IGAS)* – General Inspection of Health Activities (IGAS) – for supervision and inspection. Moreover, the DGS is responsible for the creation and maintenance of a system of quality and safety for every stage of the transplantation process; coordinate audits and control measures; authorise, suspend or revoke the authorisation of procurement units and transplant units; the creation and maintenance of a notification system and management of incidents and serious adverse reactions; issue guidelines to entities and agents involved in the transplantation process and participate in the network of competent authorities provided for in no. 1 of article 19 of the Directive, supervising the international exchange of organs.

The IPST is in turn recognized as the entity responsible for the strategic planning of national transplant needs, for giving a prior opinion under the authorisation procedure for the procurement units and transplant units, as well as ensuring the functioning of the Portuguese Transplantation Registry (RPT). The IPST may also instruct the issuing of guidelines or data information at the request of the European Commission.

The solidarity value presiding the donation is indeed best safeguarded through the promotion of compliance with the conditions that ensure the maximisation of quality in the use of the organs, recognizing the importance of a structure that acts as the guarantor to defend both vulnerable citizens' rights and citizens who donate organs in a selfless and benevolent manner.

The breadth and complexity of coordination between the different responsible entities verified in the bill call for clarification and strengthening of how such coordination shall be established, as well as what concrete cooperation mechanisms are to be implemented for this purpose.

Chapter IV – Quality and safety of the organs

In what particularly concerns the quality and safety of organs for transplant, the bill lays down that the procurement units, transplant units, the offices coordinating procurement and transplant and the blood and transplantation centres should establish and maintain a system of quality and safety in the context of their activities, in accordance with what is established nationally by DGS, in particular procedures for:

- Verification of the donor's identity, as well as the verification of information relating to consent, authorisation or absence of objections from the donor or his/her family members;

- Verification of prior characterization of organs and donors, in accordance with the minimum and supplementary data to be collected in the forms attached to the bill – in this case, in the event of an emergency, organ transplant is exceptionally assumed for which the data are incomplete, the value of life surpassing the risk-benefit analysis given the impossibility to ensure total quality and safety of the organ. With regard to obtaining information in the case of a deceased donor, the need to contact the family in an appropriate manner is ethically imperative, while respecting their dignity and particular vulnerability.

- Organ procurement, to be made in suitable conditions and in accordance with the standards of good clinical practice, and that in the case of deceased donor must be performed under the advice and guidance of a hospital donation coordinator.

- Preservation, packaging, labelling and transport of organs, performed by licensed entities and monitored appropriately and in a timely manner, with the labelling of containers providing suitable and sufficient information to the professionals in charge of implanting the organ, in the case of transport between health establishments.

- Notification and management of incidents likely to affect the quality or safety of organs and serious adverse reactions observed during or in the follow-up to transplantation, notifying the DGS to monitor and issue the necessary alerts so that the appropriate measures are taken, particularly in the case of exchange of organs between Member States.

- Traceability – the possibility to monitor and identify the route of organs from donors to recipients, and vice versa, becomes essential given the impossibility of completely eliminating the risk of transmission of diseases and contamination of the preserved organ.

Traceability also allows to monitor and detect any illegal or unethical uses of preserved organs, contributing to the prevention of organ trafficking. The implementation of a uniform system of traceability, certainly safeguarding the safety and confidentiality of personal data, is essential for the exchange and the fair allocation of organs of human origin. In fact, this exchange can only be authorised subject to compliance with the conditions of full traceability.

Due to its relevance, caution is recommended when the DGS makes agreements with organisations at European level for the exchange of organs, as provided for in article 20 of the Bill under consideration; such organisations may include both public entities and private non-profit ones as long as officially recognized, and the same degree of requirement for traceability should be extended to them.

- Medical follow-up after the donation and procurement process – the appropriate medical follow-up, both of the living donor and the recipient, is an essential element in relation to the management of safety and quality in organ transplantation. It is also a procedure done in the best interest of restoring the health of those individuals and of scientific knowledge; an essential aspect is to know the duration time of a transplanted organ and the circumstances under which this occurred. The nature and duration of that follow-up, which can transcend that needed for recovery from the intervention, should depend on the nature of the intervention and the expected impact on the health of each person.

However, whilst respecting the autonomy of the person, competent and capable of making a free and conscious decision, it should be noted that the longer-term follow-up should be provided by means of appropriate information, it being the prerogative of the donor, and even of the recipient, to refuse the follow-up and long-term monitoring, though with evident loss to the acquisition of updated scientific knowledge.

- Safety and confidentiality of the personal data of donors and recipients – in its Opinion 45/2012 on the same matter[5], the *Comissão Nacional de Proteção de Dados* (CNPD) – Portuguese Data Protection Authority – also considered 'adequate, relevant and not excessive in relation to the purpose for which they are intended', the personal data to be dealt with within the scope of the Bill now under consideration. However, it warns of the need to clarify the mechanisms of coordination between the entities involved and the circuits used by personal information.

[5] Case no. 8022/2012, available at http://www.cnpd.pt/bin/decisoes/decisoes.asp?primeira_escolha=2012&segunda_escolha=40.

The CNECV believes it is still necessary to clarify permissions and the degree of access to data by different professionals and entities involved, as well as define the specific mechanisms to guarantee the safety of the same data.

- It was also considered essential to the pursuit of quality and safety of transplantation – which is positively valued in the Bill under consideration – the exercise of functions by qualified professionals with on-going training, including best practices, to whom updated task descriptions are assigned.

Chapter V – Protection of both donor and recipient, and donor selection and evaluation.

The consent regime established in articles 7 and 8 of Law no. 12/93 is referred to here. In the case of living donor, as in the case of the recipient, obtaining the free and informed consent should be preceded by adequate and intelligible information, particularly on potential risks, benefits and consequences, and to prevent as far as possible the emotional duress on the living donor, particularly among family or friends. In the case of *post-mortem* donor, the rule of presumed consent is established, in recognition of an opting-out regime on the assumption of adequate information available to the public about the possibility of expressing the unavailability for the donation and what is the procedure for that purpose.

In the special case of donors that are minors or disabled adults, the supply regime for disability provided for in paragraphs 3 to 6 of article 8 of Law no. 12/93 is repeated. Note here the additional need for agreement of the minors with the capacity to understand and demonstrate their will.

Given their relevance, the special restrictions on admissibility of the donation or procurement in minors or other disabled people laid down in paragraphs 4 and 5 of article 6 of the same law should find reinforcement in the bill now under consideration, as they affect their eligibility as donors. Thus, it becomes essential to evaluate the therapeutic necessity for transplantation whilst safeguarding the best interests of these people, the most vulnerable. In this regard, see the provisions in article 20 of the Convention on Human Rights and Biomedicine, in force in national law as already mentioned.

Donor evaluation admits surpassing the value of physical integrity in the cases where the donation presents an unacceptable risk to health, in recognition of the primacy of the ethical principle *primum non nocere* already established in paragraph 7 of article 6 of Law no. 12/93.

One has to emphasise the importance of providing intelligible, appropriate, sufficient, accurate and independent information to the donor, both with regard to risk, consequence and possible side effects,

and with regard to selection and eligibility as donor, including the medical acts necessary for prior evaluation of their state of health.

It is true that the consent, recognized as an expression of individual, free, autonomous and informed will, as expressed by a competent person, presupposes the possibility of revocation at any time prior to donation. Such a possibility, as well as the consequences of that revocation, should be addressed in the Bill under consideration.

Chapter VII – Infractions and penalties

Article 23 of the Directive to be transposed prescribes that 'Member States shall establish the system of penalties applicable in the event of infringement of the national legislation adopted pursuant to this directive and shall take the necessary measures to ensure the appropriate application. The penalties thus established must be effective, proportionate and dissuasive'.

In accordance with Chapter VII of the Bill under consideration, the establishment of minor, serious and very serious administrative offence is thus established. Specifically in the context of offenses relating to personal data, confidentiality and safety of data processing, paragraph 1 of article 21 of the Bill determines that the regime of administrative offenses laid down in Law no. 67/98 of 26 August (Personal Data Protection Law) is applicable.

As it is not up to this Council to comment on specific sanctioning regimes or on the gradation of the infractions provided for, it will always be said that not all administrative offenses considered are directly related to the protection of personal data – see, for example, the requirements in articles 7(3) or 10(1) of the Bill under consideration.

Thus, it is suggested to clarify that, in the part not specifically related to the area of protection of personal data, this be referred to the *Regime Geral das Contraordenações* (General Regime of Administrative Offenses), laid down in Decree-Law no. 433/82 of 27 October, as amended by Decree-Law 356/89 of 17 October, by Decree-Law no. 244/95 of 14 September, and by Law no. 109/2001 of 24 December.

On the other hand, the content and importance of the proposed provisions, particularly its consequences for individuals and society, may invoke in some cases a more serious assessment of the facts,

particularly in terms of criminal offense – see, for example, article 19(1) of the Bill. The possibility of cumulation of offenses is provided for both in article 39 of the Personal Data Protection Law, and in article 20 of the General Regime of Administrative Offenses.

IV – CONCLUSION AND RECOMMENDATIONS

Taking into account all the above, and considering that it is of relevant ethical value to promote coherent and uniform legislation that guarantees the quality of the acts of transplantation, as well as safeguarding the health and integrity of both donors and recipients, and without prejudice to further consideration by the Council in the Parliamentary discussion:

1. The present Draft Bill does not raise substantial ethical objections, since there remain the fundamental aspects of respect for autonomy and integrity, information and consent, gratuitousness and beneficence.

2. However, the coherence of the Bill with regulations included in previous legislation is recommended, namely the possibility of updating Law 12/93, in order to avoid the dispersion of regulations.

3. The manner of coordinating the competencies of the competent authorities must still be defined clearly, in particular the specific coordination to be established between the IPST and DGS, and between the latter and the IGAS in terms of inspection and sanctioning functions, in order to avoid situations of overlapping or cooperation failures that result in loss to the citizens.

4. In the special case of donors that are minors or adult donors who are disabled, the special restrictions on admissibility of the donation or procurement in donors that are minors or other disabled persons should find reinforcement in the Bill under consideration.

5. The system for recording and safeguarding the confidentiality of donor and recipient identification should receive detailed regulations, clarifying the permissions and the degree of access to data by the different professionals and entities involved, as well as defining the specific mechanisms to guarantee data safety.

Lisbon, 21 September 2012

The President,
Miguel Oliveira da Silva

The present Opinion was approved in the plenary meeting of 21 September 2012. Besides the Chairman, the following Counsellors were present:

Ana Sofia Carvalho; Carolino Monteiro; Francisco Carvalho Guerra; Isabel Santos; José Germano de Sousa; Lucília Nunes; Maria de Sousa; Michel Renaud; Pedro Nunes; Rosalvo Almeida.
The Executive Secretary, Cíntia Águas, was rapporteur of the Opinion.