NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

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Opinion on Government Bill no. 219/XII, which makes the first amendment to Law no. 36/2013 of 12 June 2013, which approves the regime for guaranteeing the quality and safety of human organs for transplantation into the human body

(July 2014)

I - INTRODUCTION AND BACKGROUND

The Parliamentary Health Committee addressed a request to the National Council of Ethics for the Life Sciences (CNECV) relating to Government Bill no. 219/XII (3rd), hereafter "the Bill", which "makes the first amendment to Law no. 36/2013 of 12 June 2013, which approves the regime for guaranteeing the quality and safety of human organs for transplantation into the human body, in order to ensure the protection of human health, transposing Commission Implementing Directive 2012/25/EU of 9 October 2012, laying down information procedures for exchange".

As this is a Government bill that implements the transposition of a Commission Directive, and taking into account the reflection[1] recorded by the CNECV in previous Opinions, the reply to the request submitted shall consist of a particular consideration of the questions posed.

To provide the ethical and legal framework for the matter under consideration, we mention: the Convention on Human Rights and Biomedicine[2] and the Additional Protocol to the Convention on Human Rights and Biomedicine signed by Portugal, with regard to the transplantation of organ and tissues of human origin; the Charter of Fundamental Rights of the European Union, particularly Article 3[3]; and the UNESCO Universal Declaration on Bioethics and Human Rights[4].

II - ANALYSIS OF THE LEGISLATIVE PROPOSAL

The proposal in question envisages, in summary, amendments to the Articles contained therein, under the following terms:

- A paragraph 2 is **added** to **Article 1**, regarding the subject matter, and reads *"This Law also regulates the information procedures necessary for the cross-border exchange of human organs intended for transplantation within the European Union, establishing procedures for the transmission of information on organ and donor characterisation, procedures for the transmission of the necessary information to ensure the traceability of organs, and procedures for ensuring the reporting of serious*

[1] The CNECV has issued Opinions on the ethical issues raised by the "donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells", and "traceability, notification of serious adverse events and reactions and technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells", namely in Opinions nos. 54/CNECV/2007, 55/CNECV/2008 and, most recently, in Opinion no. 65/CNECV/2012.

[2] (Council of Europe), ratified by Portugal on 3 January 2001 and in force in the Portuguese legal system since 1 December 2001.

[3] OJ C 83 of 30.03.2010, p. 389 *et. seq.*

[4] Adopted on 19 October 2005 by the 33rd session of the General Conference of UNESCO.

adverse events and reactions, transposing Commission Implementation Directive 2012/25/EU of 9 October 2012 into the national legal system";

- A paragraph 2 is **added** (the previous paragraph 2 remains, and becomes paragraph 3) to **Article 2**, scope of application, "*2. The provisions of this Law shall also apply to the cross-border exchange of human organs intended for transplantation within the European Union, and with third countries with which Portugal has previously established agreements.*

- Definitions are **added** to **Article 3**, relating to definitions, for "delegated body", "specification of the organ", "Member State of origin", "Member State of destination" and "National donor/recipient identification number";

- In competent authority, **Article 5**, on the designation and functions of the competent body, "The Directorate-General of Health (DGS) is the competent authority and shall be responsible for checking compliance with the requirements established in this Law throughout Portugal, without prejudice to cooperation with the Inspectorate-General for Health Activities (IGAS) in matters of supervision and inspection", the following wording is **introduced**: "*and to the competences of the IPST* [Portuguese Blood and Transplantation Institute]*, in matters of coordinating the activity of procurement and transplantation, strategic planning of responses to national needs and authorisation of the import and export of organs*"; in functions of the competent body, paragraph e), "establishing a reporting system" is **amended** to "monitoring the information contained in the reporting system"; a paragraph 3 is added – "*The competences established in the previous paragraphs may be delegated by means of a prior permission order issued by the member of the Government responsible for the health area*.";

- In **Article 6**, relating to the registry and reports of procurement centres and transplantation centres, "The RPT (Portuguese Transplant Registry) shall include the data referred to in Articles 13, 14, 17 and 18", paragraph 2 **is amended to read** "The RPT shall include a component of reporting and management of serious adverse events and reactions and shall contain the data referred to in Articles 13, 14, 17 and 18"; paragraph 5, which reads **"**The IPST shall guarantee the DGS access to the information contained in the RPT" **is amended to read as follows**: "The IPST shall guarantee the DGS prompt warning and access to the information contained in the RPT, namely when adverse events and reactions occur, and the DGS shall be informed of the respective nature, cause, measures adopted and consequences";

In **Article 12**, Transportation of organs, the final part of paragraph 1 is **removed**, and instead of "1 - The bodies, entities and companies involved in the transportation of organs shall establish operational procedures to ensure the integrity of the organs during transportation and an appropriate transport time, in accordance with the system referred to in Article 9. The bodies, entities and companies mentioned shall be subject to licensing and inspection under terms to be defined by a Ministerial Order issued by the member of the Government responsible for the health area", the text

reads: "*1 - The bodies, entities and companies involved in the transportation of organs shall establish operational procedures to ensure the integrity of organs during transportation and an appropriate transport time, in accordance with the system referred to in Article 9.*";

- In **Article 13**, Traceability, there is an **amendment** to paragraph 5: "In the case of an exchange of organs between Member States, the transmission of the data necessary for traceability and the information on organ and donor characterisation, referred to in paragraph 3, shall be done as follows:

a) The specification of the organ; b) The national donor identification number; c) The date of procurement; d) The name and contact details of the procurement centre." **instead reads**: "5 - In the case of an exchange of organs with another Member State, the transmission to the competent authority or delegated body, by the DGS, of the data necessary to ensure traceability and the information on organ and donor characterisation, referred to in paragraph 3, shall guarantee: a) The specification of the organ; b) The national donor identification number; c) The date of procurement; d) The name and contact details of the procurement centre.";

- Also in Article 13, paragraph 6, it is laid down that the DGS "shall perform the procedures necessary to allow the competent authority or delegated body of the Member State of origin to be informed of the following: a) The national recipient identification number or, if the organ was not transplanted, its final use; b) The date of transplantation, if applicable; c) The name and contact details of the transplantation centre."

- In **Article 14**, instead of the DGS it becomes the IPST that, under the terms of Article 6, shall establish immediate communication of adverse events (subparagraph a)) and reactions (subparagraph b)), which now includes (further to procurement, testing, characterisation, preservation and transportation) the transplantation of organs; furthermore, immediate warning and notification of the DGS about serious adverse events and reactions is assigned to the IPST (instead of the DGS); also, in paragraph 3, the monitoring and management of notifications passes to the IPST. Paragraph 5 is also amended, notification in the event of serious adverse events or reactions in situations of organ exchange, and the procedure is established in the new subparagraphs:

"a) *When the DGS is notified of a serious adverse reaction or event that it suspects to relate to an organ that was received from another Member State, it shall immediately inform the competent authority or the delegated body of the Member State of origin and shall transmit to it an initial report with the information set out in Annex III to this Law, of which it is an integral part, if that information is available; b) The DGS shall immediately inform the competent authorities or delegated bodies of each Member State of destination and shall transmit them each an initial report containing the information set out in Annex III to this Law, whenever it is notified of a serious adverse event or reaction that it suspects to be related to a donor whose organs were also sent to other Member States; c) When additional information becomes available following the initial report, the DGS shall transmit it immediately; d) Save for a valid reason, the DGS shall, within three months of the initial report*

transmitted pursuant to subparagraphs a) and b), transmit to the competent authorities or delegated bodies of all the Member States of destination, a common final report containing all the information set out in Annex IV, informing the IPST of that report; e) The final report, containing the information set out in Annex IV to this Law, shall be drawn up after collecting relevant information from all the Member States involved." As a consequence of the provisions, **two annexes are added**: III (Initial report for suspected serious adverse events or reactions) and IV (Final report of serious adverse events or reactions).

- **Article 18-A is added -** "*Common procedural rules. 1 - The information transmitted pursuant to this Law between competent authorities or delegated bodies shall: a) Be transmitted in writing either electronically or by fax; b) Be transmitted in a language mutually understood by the sender and the addressee or, in the absence thereof, a mutually agreed language, or, in the absence thereof, English; c) Be transmitted immediately; d) Be recorded and made available upon request; e) Indicate the date and time of the transmission; f) Include the contact details of the person responsible for the transmission; g) Contain the following reminder: "Contains personal data. To be protected against unauthorised disclosure or access. 2 - In case of urgencies, the information can be exchanged in a verbal form, in particular for exchanges pursuant to Article 14(5) and Article 19-A, and shall be followed by a transmission in writing in accordance with those Articles. 3 - The receipt of the information transmitted in accordance with the provisions of this Law shall be confirmed to the sender, in accordance with the requirements set out in paragraph 1. 4 - The bodies referred to in paragraph 1 shall be permanently available for urgent situations and shall guarantee the exchange of information pursuant to this Law without undue delay*.";

- **Article 19-A is added -** "*Information on organ and donor characterisation. 1 - The IPST shall ensure the transmission, in the case of organ exchange between Member States, before the organ is exchanged, of the information collected to characterise the procured organs and the donor, as specified in Article 11, to the competent authorities or delegated bodies of the potential Member States of destination. 2 - The IPST shall ensure that, where some of the information to be transmitted in accordance with paragraph 1 is not available at the time of the initial transmission and becomes available later, it is transmitted in due time to allow for the necessary medical decisions to be made. 3 - For the purposes established in the previous paragraphs, the GCCTs (i.e. "the coordinating offices for procurement and transplantation") shall be responsible for directly and immediately transmitting the information required to the transplantation centre. 4 - The DGS shall be notified immediately of the transmission referred to in the previous paragraph, and it shall communicate with the competent authority or delegated body of the Member State of destination*."

Article 19-B is also added - *"Interconnection between Member States 1 - The DGA, as the competent authority, shall communicate to the Commission the contact details necessary, for which the relevant information for the purposes of Article 13(5) and (6), Article 14 and*

Article 19-A shall be transmitted, which includes the name, telephone number, e-mail address, fax number and postal address of the body. 2 - The DGS shall keep up to date the information on the list that the Commission makes available to the Member States with all the competent authorities and delegated bodies appointed by the Member States in accordance with paragraph 1."

Article 24-A is also introduced – Fees: "*1 - Fees shall be owed for the consideration of requests to authorise the activities of procuring and transplanting organs performed by hospitals and medical institutions, whether public or private, to be paid and charged under the terms defined by a Ministerial Order issued by the members of the Government responsible for the areas of health and finance. 2 - The allocation of revenue shall be defined by the Ministerial Order referred to in the previous paragraph, and a minimum of 60% of the revenue shall be due to the Directorate-General of Health.*"

The text of Articles 4, 7, 8, 9, 10, 11, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 and 25 remains unaltered. The annexes: III (Initial report for suspected serious adverse events or reactions) and IV (Final report of serious adverse events or reactions) establish the points for the two Reports.

Report III concludes with "Measures taken immediately". It is important to add an immediate assessment of those measures, in light of the time foreseen (3 months) between the initial report and final report.

Similarly, it appears to be useful for the final report (Annex IV) to include all the information given in the relevant initial report (Annex III) or, alternatively, for the additional information established in Annex IV to be added to the initial report (which would be attached) in order to avoid repetition and to ease interpretation of the information provided, above all regarding the effectiveness of the procedures.

III - CONCLUSION AND RECOMMENDATIONS

The ethical structure in this matter is founded on fundamental values of respect for the dignity, autonomy and integrity of the person, by safeguarding his/her health, safety and privacy, as well as respect for his/her vulnerability. The safety and quality of the procedures are, likewise, ethical references that justify the need to regulate the information procedures necessary for the cross-border exchange of human organs intended for transplantation within the European Union, establishing procedures for transmitting information on donor and organ characterisation, procedures for the transmission of information needed to ensure the traceability of organs and procedures intended to ensure the notification of serious adverse reactions and events.

Thus, the proposed amendments to the Law concern, significantly, competences and procedures, including the management of the RPT (Portuguese Transplant Registry); the reference to

the immediate warning and access to information should be highlighted, namely when adverse events and reactions occur. It is considered appropriate to include transplantation (further to the procurement, testing, characterisation, preservation and transportation of organs) and it should be noted that the common procedural rules include the reminder "Contains personal data. To be protected against unauthorised disclosure or access." This note is particularly relevant, since the proposal involves not only cooperation between two bodies for the management of relevant information (IPST, at national level; DGS for contact with other countries in the European Union), but also the possible transmission of personal data outside Portugal. This interaction should be clear, in order to ensure the privacy of those involved and their families.

It is recommended that the reports to be prepared (Annexes III and IV) can be coordinated in order to avoid repetition and to ease interpretation of the information provided, above all regarding the effectiveness of procedures. It is further suggested that Annex III, which concludes with "Measures taken immediately" can include an immediate assessment of those measures.

In light of the above, and considering the relevant ethical value of safeguarding the health and integrity of the people involved, as well as the reporting and monitoring of adverse events and reactions, no ethical objections are raised concerning this Government Bill, provided that the fundamental aspects of technical accuracy and strict compliance with the parameters established are maintained.

Lisbon, 21 July 2014

The President, Miguel Oliveira da Silva

Rapporteurs: Members João Ramalho-Santos and Lucília Nunes.

Approved in plenary meeting on 21 July 2014. In addition to the President, the following Members were present:

Agostinho Almeida Santos; Ana Sofia Carvalho; Carolino Monteiro; Duarte Nuno Vieira; Francisco Carvalho Guerra; Isabel Santos; Jorge Sequeiros; José Germano de Sousa; José Lebre de Freitas; Lígia Amâncio: Lucília Nunes; Maria de Sousa; Maria do Céu Patrão Neves; Michel Renaud; Pedro Nunes; Rita Lobo Xavier; Rosalvo Almeida.