



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

REPORT 25/CNECV/98

ON THE DRAFT BILL REGULATING THE THERAPEUTIC USE OF HUMAN-ORIGIN BIOLOGICAL PRODUCTS AND OF BIOTECHNOLOGY

The therapeutic use of human-origin biological products and of Biotechnology is a matter having appreciable ethical relevance in its diverse facets, from collection to application, which is further reinforced by new facts relating to the remarkable developments in technology and to the recent emergence of transmission of serious diseases due to non-existence of efficacious treatment or adequate prophylaxis. Consequently, the prevention of these risks is the only useful measure, and one that must be included in any legislative instrument aiming to regulate the therapeutic use of such products or their technological derivatives.

We shall refer the biological products (1), the therapeutic purposes (2), and the products obtained through biotechnology (3) to which the Draft Bill under appraisal applies:

- 1 - Organs (kidney, heart, liver), organ fragments (liver, cornea), tissues and by-products (bone marrow, blood, plasma, human albumin, cryoprecipitates and skin – the latter with exceptional character), erythrocytes, platelets, staminal cells from peripheral blood and the umbilical chord. Only heterologous biological products will be referred, since autologous products do not entail the same ethical reservations, for their collection and reuse depend only on the free informed consent of the donor-recipient. Also, we shall not refer semen, since its collection, conservation and therapeutic use have been already the object of an Opinion by this Council.¹
- 2.1 - Transplantation or grafting – kidney, heart, liver, liver fragment, skin, cornea and bone marrow.
- 2.2 - Transfusion – blood, erythrocytes, platelets, staminal cells, plasma and their by-products.
- 3- “Human-origin biotechnological products” must be regarded as medicaments produced by industrial technology based on genetic engineering, and they are essentially those mentioned in Decree-Law 72/91.

Given the potential dangers of these therapeutic applications, a National Monitoring (Surveillance) System becomes indispensable, having as a national-level structure the Portuguese Blood Institute (IPS), overseeing blood, plasma and their by-products, mature and staminal circulating cells, both peripheral and from the umbilical chord.

In this last case, informed consent by the Mother is required.

¹ *Report-Opinion 3/CNECV/93.*



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To the IPS shall fall the accreditation not only of all the units involved in technologies such as collection, conservation and the different procedures for the different blood components, but also of those units that practice more sophisticated techniques of risk diagnosis – for instance, the determination of viral load by PCR² – the transfusion of staminal cells, and the implementation of the fast-developing techniques that diminish virus transmission ability.

The National Transplantation Organisation (ONT) will act in analogous manner with regard to the transplantation of organs or parts of organs – from collection to transplantation – and to the system analysis of post-transplantation results in terms of costs/benefits/efficacy. By acting in association with the several Medical Societies, the ONT may constitute a Forum for debating the multiple ethical problems these techniques may raise.

The Pharmacy and Medical Drugs Institute (INFARMED) will be the third pillar of overall co-ordination. Since, at this moment, all medicaments produced through biotechnology are imported, INFARMED's first task must be the assurance of their quality, followed later by the evaluation and recording of any undesirable effects after their introduction in the market. It must also supervise the circuits of medicaments such as erythropoietin, which may be supplied only by hospitals under the National Health Service.

This conception presupposes that an integrated communications network (Intranet) will be set up among the several Health Care Services and the administrative and technical Co-ordinating Bodies, pursuant to the conclusions of the document *Reflection on Health*.³ If that recommendation is accepted as a priority objective, all the health-related data of each user are to be electronically recorded in a personal card. In that case, there must be rapid measures to lessen to the utmost the vulnerability of the system as regards the confidentiality of the personal data electronically recorded and transported. This system will obviate the need for a specific, voluntary card for recipients.

Lisbon, the 5th of May, 1998

The Reporter,

A. Falcão de Freitas, Ph.D.

² JHN: I do not know this abbreviation. In English, it is possibly RCP.

³ Daniel SERRÃO et al, *Reflection on Health – Recommendations for a Structural Reform*. (English version: José Henrique Neto). Porto, Conselho de Reflexão sobre a Saúde, Jan. 1998.



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OPINION 25/CNECV/98

**ON THE DRAFT BILL
REGULATING THE THERAPEUTIC USE
OF HUMAN-ORIGIN BIOLOGICAL PRODUCTS
AND OF BIOTECHNOLOGY**

The National Council of Ethics for the Life Sciences (CNECV) was requested by Her Excellency the Minister of Health to emit an Opinion on the ethical aspects of the Draft Bill regulating the Therapeutic Use of Human-Origin Biological Products and of Biotechnology. Consequently:

1. Considering that:
 - 1.1. The CNECV has issued repeated pronouncements on matters similar to those raised by this Draft Bill, especially with regard to informed consent, confidentiality and equity;
 - 1.2. A structural reform in Health has been proposed, which provides for an electronic medical data bank, set up as an on-line network;
 - 1.3. The legislation that regulates the therapeutic application on human beings of human-origin biological products and of biotechnology must bear on concrete and well known matters;
 - 1.4. Human-origin biological products may be put to different uses;
 - 1.5. The situation of minors and of incapable adults as recipients, as well as the use for therapeutic purposes of foetal fragments must be considered explicitly.
2. The National Council of Ethics for the Life Sciences emits the following Opinion:
 - 2.1. It is ethically unacceptable to issue legislation on therapeutic products which are not specified in the Draft Bill (Art. 2, a, VII and IX, and also Art. 3, §1, d, and § 2, b);
 - 2.2. There must be a clause making it obligatory to inform the donor of the purpose of the collection of biological products;
 - 2.3. When the heterologous donor is a minor or an incapable adult, the collection of products must be carried out in exceptional manner and with due ethical justification;



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2.4. It is not ethically acceptable that the possibility of minors or incapable adults being recipients should be omitted;

2.5. As regards the utilisation of tissues and organs extracted from dead fetuses, consensual ethical principles exist, such as the parents' informed consent, reliable diagnosis of foetal death, separation between the physician who treats the patient or does the abortion and the team that will use the foetal tissues or organs, and a clear separation between the decision to do the abortion and the request to use tissues or organs that are to be extracted from the aborted foetus. Given the difficulty of applying hard and fast ethical criteria to every stage in this type of intervention, a move to legislate seems premature; a moratorium on this matter would be appropriate.

3. Also on ethical grounds, it is the view of this Council that:

3.1. The voluntary recipient card proposed should be replaced by the future individual health card, which will permit access to each personal health data file. The latter should include indication of recipient status;

3.2. The National Surveillance System that will ensure the safety and prevent undesirable effects of, and adverse reactions to human-origin biotechnological products and biotechnology should be part of the future integrated national network of the Portuguese Health System;

3.3. The – updated – description of the “*human-origin biotechnological products*” must be included in the text of the projected legal instrument, instead of being referred to the Appendix to Decree-Law. no. 72/91;

3.4. The access to the use of these products must comply with stringent criteria of equity, to be formally instituted.

Lisbon, the 5th of May, 1998

The President of the National Council of Ethics
for the Life Sciences

Prof. Luís Archer, Ph.D.



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Documentation for Opinion 25/CNECV/98

*[Cover Letter from the Minister of Health
to the President of the National Council of Ethics for the Life Sciences, Prof. Luís Archer,
dated Lisbon, the 6th of January, 1998]*

Most Excellent Prof. Luís Archer,

The Work Group appointed by my Order of 97.6.9 to study the Therapeutic Use of Human-origin Biological Products and of Biotechnology has presented its conclusions on the task with which it was charged, and on that basis the Bill enclosed herewith was drafted, which I take the liberty of submitting to your consideration, pursuant to Article 7, subparagraph c) of Law no. 14/90, requesting that an Opinion be emitted by the Council over which you so worthily preside.

The ethical dimension of the issues under study leads me to believe that the Council's interest in the appreciation of the legal text may be enriched by an analysis of the Acts of the Meetings of the Workgroup, which I am also forwarding to Your Excellency.

I am most grateful indeed, Professor, for your collaboration in this matter, and I take the opportunity to extend to you my best regards and my personal admiration and esteem.

ss: Maria de Belém Roseira



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Presentation of the grounds

Law no.12/93 of the 22nd of April, applying to acts whose aim is the donation or harvesting of human-origin tissues or organs, for either diagnostic or therapeutic and transplantation purposes, represents a significant contribution to the juridical safeguarding of health protection, to respect for individual rights and guaranties, and to the discipline and control of the use of human-origin biological products.

While, on the one hand, it has become necessary to regulate the therapeutic use of human-origin products and other materials, so as to safeguard the quality of the acts performed for the benefit of the recipients of such products and materials; on the other hand, when nearly five years have elapsed since Law no.12/93 came into force, it is important to elaborate norms providing for acts or situations adjacent to those within the scope of that Law, so as to fill the legal void in which lie such acts and situations and thereby permit the imposition of juridical uniformity on the therapeutic use of human-origin biological and biotechnological products.

Since it is our view that it is of the utmost importance to define the scope of applicability of the norms contained in the present Bill, we propose a definition of the legal concept of human-origin biological products and materials, widened herein to include human-origin products and materials not encompassed by the concept of organs and tissues, and we list their respective therapeutic purposes.

Furthermore, it is necessary to establish the technical conditions required to carry out the harvesting of biological products and materials, which may be practiced only in harvesting centres, duly authorised so long as they fulfil certain mandatory requirements. On the other hand, with a view to assuring the quality of human-origin tissues, or fragments thereof, from the time they are harvested up to their eventual utilisation, we also call for technical units known as "tissue banks".

Considering the imperative necessity of ensuring safety, and of preventing adverse reactions to human-origin biological and biotechnological products, the present Bill provides for the creation of a national surveillance system, which must be fully efficacious and functional for the recording and analysis of all undesired effects resulting from the therapeutic use of such products and materials, if need be with reference to their donors or recipients.

We also give legislative existence to an institutional instrument – the Portuguese Transplantation Organisation – which must establish the necessary norms for the articulation of the entities severally engaged in the harvesting and transplantation of organs, tissues, and fragments thereof, and must also promote the necessary conditions for the correct organisation of their respective activities.

Lastly, we provide for the creation of a card for recipients of biological products, which should permit immediate certification of the card-holder as recipient, bearing in mind that,



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owing to the primacy of individual freedom, the card is to be issued only by request of the person concerned and, consequently, is to be presented at the holder's discretion.

Therefore:

Pursuant to subparagraph 1.d) of Article 200 of the Portuguese Constitution, the Government now brings before the Assembly of the Republic [Parliament] the following Bill:

Article 1 Objectives

The present law establishes the juridical regime of the therapeutic use of human-origin biological and biotechnological products.

Article 2 Definitions

For the purposes of the present legal text, it is considered that:

a) "Human-origin biological products", hereinafter referred to as "biological products", are those products whose composition or processing involves cells, tissues, bodily fluids or other biological materials having human origin, and they comprise:

- i) Blood and its components;
- ii) Products derived from blood;
- iii) Proteins or fragments thereof extractable from blood;
- iv) Peripheral haematopoietic stem cells;
- v) Bone marrow cells;
- vi) Chord and other foetal tissue cells used for therapeutic purposes;
- vii) Bodily fluids and cellular suspensions, when used for therapeutic purposes;
- viii) Organs, tissues and/or fragments thereof, when used for therapeutic purposes, regardless of the intention with which their harvesting was done and of the time that elapses until their utilisation;



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ix) Other therapeutic products whose composition or processing involves the use of human-origin biological materials not provided for in the preceding subparagraphs.

b) "Human-origin biotechnological products", hereinafter referred to as "biotechnological products", are those products derived from human-origin biological materials whose manufacture involves the biotechnological methods provided for in the "APPENDIX" to Decree-Law no.72/91 of the 8th of February, or other such products that constitute an important innovation.

Article 3

Use of biological and biotechnological products

1. The harvesting, preparation, conservation and distribution of biological products is meant for any of the following uses:

- a) Transfusion;
- b) Transplantation;
- c) Manufacture of medicinal products;
- d) Manufacture of other therapeutic products.

2. The harvesting, preparation, conservation and distribution of biological materials for the production or processing of biotechnological products is meant for any of the following uses:

- a) Manufacture of medicinal products;
- b) Manufacture of other therapeutic products.

Article 4

Harvesting

The harvesting of those products and/or materials to which the present legal text applies may be carried out only under medical guidance and vigilance, in accordance with the respective *leges artis*, and only at centres for the harvesting of biological products or materials.

Article 5

Harvesting centres



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1. The harvesting centres provided for in the preceding Article must have technical conditions for carrying out the harvesting procedures and for assuring the quality of those products and materials, and such centres may function:

a) In the case of transfusable biological products – within services integrated in the national network of blood transfusion, and also within private health units or laboratories, provided these are duly licensed.

b) In the case of transplantable biological products – within hospitals integrated in the National Health Service, forensic medicine institutes and private health units, by agreement with the offices that co-ordinate organ harvesting and transplantation, provided these establishments are duly licensed;

c) In the case of biological products or materials for the manufacture of medicinal products, other therapeutic products or biotechnological therapeutic products – under the responsibility of the holder of the manufacturing license in each case, on its own or supported by the entities referred in the preceding subparagraphs.

2. The harvesting centres are to be authorised by the Ministry of Health and subjected to periodic evaluation of their activities by that same Ministry.

3. Harvesting centres already in functions do not require the authorisation provided for in the preceding paragraph, without prejudice to the evaluation referred in that same paragraph and to compliance with the prerequisites referred in the paragraph that follows.

4. The prerequisites for authorising the operation of harvesting centres are to be set by the Government through a specific legal instrument.

Article 6 Tissue banks

1. The preparation, conservation, distribution and quality assurance of the tissues or fragments thereof, after harvesting and up to their utilisation, are to be assured by tissue banks with access to data concerning the provenience, conditions of conservation and destination of the tissues or fragments thereof.

2. The prerequisites for the authorising the operation of tissue banks are to be set by the Government through a specific legal instrument.

3. To tissue banks shall apply, with the necessary adjustments, the authorisation and evaluation of activities provided for in paragraphs 2 and 3 of the preceding Article on harvesting centres.

Article 7 National surveillance system



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A national surveillance system is created hereby, to assure quality and prevent adverse reactions to biological and biotechnological products.

2. This national surveillance system is to be assured, in terms defined by Government, by surveillance centres which shall have the following incumbencies, for the purposes set forth in the preceding paragraph:

- a) To record unexpected or undesirable effects resulting from the therapeutic utilisation of biological and/or biotechnological products;
- b) To record data that permit establishing a connection between donors of biological products or materials used for the manufacture of biotechnological products, and the recipients of such products;
- c) To analyse the informations referred in the preceding subparagraphs and promote the communication of the results obtained to the entities that directly intervened in the acts also referred therein;
- d) To propose, whenever the case calls for it, the appropriate measures to be taken so as to eliminate or contain any adverse effects resulting from the utilisation of biological or biotechnological products.

3. The surveillance procedures to which the stipulations of the preceding paragraphs apply are to be approved by Government through a specific legal instrument.

Article 8 Consent

1. The harvesting of products within the scope of the present legal text may only be carried out:

- a) In the case of harvesting from a live donor – after the donor's free, informed and unequivocal consent;
- b) In the case of harvesting from a cadaver – after verification of the inexistence of a record of its unavailability for the donation in question, pursuant to Law no.12/93 of the 22nd of April, and to Decree-Law no.244/94 of the 26th of September.

2. For the purposes of subparagraph a) of the preceding paragraph, the consent must be in writing and it must be preceded by intelligible information on the consequences and possible risks of the act that will be carried out; in any situations not provided for herein, the rules contained in Article 8 of Law no. 12/93 of the 22nd of April shall apply.



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3. The recipients of biological products must produce their consent as per subparagraph 1.a) above and the preceding paragraph, except when such consent can only be obtained with a delay that entails life risk or serious risk to the body or its health.

(4. Recipients who are minors.)

Article 9 Gratuity

1. The act of donation of biological products or materials may not under any circumstance be paid for or be an object of trade.

2. The agents of the acts referred in Article 3 and the establishments authorised to practice such acts may earn remuneration for the services rendered, but, in the calculation of such remuneration, no price may be attributed to the biological products or materials donated, received or used.

Article 10 Confidentiality and professional trust

1. Save for consent by the person concerned or the person's legal representative, it is forbidden to reveal any personal data about the donor or recipient of biological and biotechnological products.

2. Those who, in the exercise of their functions, come to know any personal data contained in the records pertaining to the donation, to the donors and recipients of biological and biotechnological products, are bound to professional confidentiality, even after ceasing their functions.

3. Without prejudice to criminal liability, infringement of the stipulations of the preceding paragraphs shall constitute a disciplinary and civil offense.

Article 11 Right to Assistance and Liability

1. Donors have a right, if that be the case, to free medical assistance up to their full recovery, and to be paid compensation for any harm or loss suffered that was directly caused by acts of harvesting biological products.

2. The entities in whose premises the acts provided for in Article 3 are practiced may transfer, totally or partially, their civil liability to insurance companies.

Article 12 Recipient Card



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1. Whenever the person concerned requests it, an individual card must be issued to him/her, stating his/her status as recipient of biological or biotechnological products, the name and date of administration of the therapeutic product and an identification of the clinical history file where this has been recorded.
2. The model of the recipient card is to be approved by the Government through a specific legal instrument.

Article 13 Applicable legislation

The legal norms and by-laws applying to human-origin biological and biotechnological products that do not run counter to the stipulations contained herein shall remain in force.

Article 14 Revocation provision

Article 3 of Decree-Law no. 110/83 of the 21st of February is hereby revoked.

Article 14 [sic] Final provision

1. The Portuguese Transplantation Organisation [*Organização Portuguesa de Transplantação*] is hereby created, for the guidance, co-ordination and monitoring of the harvesting and transplantation of biological products and/or materials, especially as regards their ethical aspects and the evaluation of results.
2. The structure, spheres of competence and functioning of the Portuguese Transplantation Organisation are to be determined by the Government through a specific legal instrument.

Reviewed and approved in Cabinet Meeting, on the

**The Prime Minister
The Minister of Health**



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CONCLUSIONS OF THE WORK GROUP
on
The Therapeutic Use of Human-Origin
Biological and Biotechnological Products

The Work Group appointed by Her Excellency the Minister of Health pursuant to Order no. 62/96, published in the *Diário da República*, 2nd series, on the 22nd of March, 1996, for the purpose of defining human-origin biological and biotechnological products and appreciating the possibilities of creating a national registry and a national surveillance network of such products, as well as evaluating their costs and proposing any measures necessary to the regulation of therapeutic activities, concludes:

I – Feasibility of the creation of a national registry

The members of the Work Group consider that it is feasible to create a national registry of human-origin biological and biotechnological products, although it is still open to debate how that registry is to be compiled and on what physical medium.

Recognising the limitations that exist – the great diversity of products, the possibility of their being sold and applied outside public institutions on an ambulatory basis, the non-computerisation of the services, the diversity of existing software, etc. – as well as the number and diversity of the institutions involved and the great amplitude of the data that must be entered and stored, leads the Work Group to opt (for reasons of feasibility), in the initial stages of the project, for the non-obligatoriness of entering records into a telematics network.

This registry shall include the information contained in the "Data to be recorded" specific to each class of products, as established in point VI hereunder, and the information contained in the "Recipient Card".

II – Definitions

For the purposes of the objectives proposed herein, it is considered that:

1. Human-origin biological products for therapeutic purposes are all those products whose composition or processing involves human-origin cells, tissues, bodily fluids or other biological materials.

Human-origin biological products for therapeutic products include:

- blood and its components;



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- blood-derived products;
- proteins or fragments thereof that can be extracted from blood;
- peripheral haematopoietic stem cells;
- bone marrow cells;
- chord cells;
- other foetal tissue cells that may possibly be used as transplants;
- bodily fluids and cellular suspensions, when used for therapeutic purposes;
- organs, tissues and/or fragments thereof, when used for therapeutic purposes, regardless of the intention with which their harvesting was done and of the time that elapses until their utilisation;
- all therapeutic products whose composition or processing involves the use of human-origin biological materials not provided for in the preceding subparagraphs.

2. Biotechnological products are those whose manufacture or processing involves biotechnological methods, among which we may highlight the following:

- recombinant DNA technology;
- methods involving hybridomas and monoclonal antibodies
- the controlled expression of the genes responsible for the synthesis of biologically active proteins in prokaryotic and eukaryotic cells, including altered cells from mammals
- other biotechnological processes that constitute an important innovation and are not encompassed by the preceding subparagraphs.

III – Harvesting Capacity

The harvesting of human-origin biological material for therapeutic purposes may be carried out only under medical responsibility and direct supervision, in accordance with the respective *leges artis* and in private or public health establishments of good standing.

The organ and tissue harvesting Units or Centres must be authorised by the Ministry of Health and be subject to periodic evaluation of their activities and results by that same Ministry.



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IV – Creation of a Code for Tissue Banks

Given the inexistence of specific by-laws or regulations, the Work Group proposes the creation of regulations for Tissue Banks, suggesting as a definition "the technical unit at a hospital or health establishment whose mission is to assure the quality of tissues from the time of their harvesting up to and including their use as a graft, specifically during the preparation, conservation, distribution, transportation and utilisation of such tissues."

To Tissue Banks shall fall the gathering of data about the origin, conservation and utilisation of tissues or parts thereof, which data must be forwarded to Lusotransplante.

V – Surveillance System

The National Surveillance System for human-origin biological products is made up of three National Centres:

- Centro Nacional de Hemovigilância [National Haemo-surveillance Centre], to be created, dedicated to blood and its components
- Lusotransplante, dedicated to products used as transplants
- Centro Nacional de Farmacovigilância [National Pharmaco-surveillance Centre], dedicated to medicinal products

Any adverse effects or reactions occurring in patients to whom human-origin biological and biotechnological products have been administered must be reported to the proper Surveillance Centre.

VI – Data to be recorded

The purpose of the records is to identify the donor and the recipient of human-origin biological and biotechnological products that have been used therapeutically, permitting traceability and, consequently, permitting the establishment of a surveillance system in this area.

When the product administered be blood, plasma components or derivatives, the records on the donors and their donations must be filed in such manner that, while maintaining the same degree of confidentiality regarding the donor's identity, it is possible to trace the origin of each donation, the total amount of plasma used and the results relating to the acceptance criteria and to the laboratory tests.



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For the purposes of the data to be recorded, these products have been divided into four groups:

A – Blood and components thereof

The data to be recorded are those set forth in the "Appendix" to the Decreto Regulamentar [Statutory Decree] no. 16/95 of the 29th of May.

B – Human-origin biological products used in transplantations

1. Regarding harvesting

1.1 – identification of the donor(s) of organ, tissue or fragment thereof

1.2 – informed consent by the donor, or the donor's legal representative, when the product is harvested in life. In the case of a product harvested from a cadaver there must be a written statement that no legally valid record existed of an express will not to donate tissues and/or organs. Human-origin organs and tissues or fragments thereof removed from a patient for therapeutic purposes and partially used (transformed or not) on other patients also for therapeutic purposes, may be used only after express consent has been obtained from the patient from whom it was [they were] removed.

1.3 – summary of the anamnesis and clinical, biological, microbiological, immunological or other tests held to be necessary to which the donors were subjected and which furnish the informations that permit evaluating the chances of the donors not being carriers of some transmissible disease. The absence of data referring the donor's anamnesis and the means of complementary diagnosis used must be duly justified in writing.

1.4 – Identification of the tissue or organ harvested for transplantation purposes. In the case of fragmentation into parts, such parts must be correctly identified.

2. Regarding Conservation

– in cases where the tissue or organ requires special conditions of conservation, the conditions of conservation to which it was subjected up to the date of utilisation must be mentioned.

3. Regarding the Recipient(s)

– all recipients of any tissue, organ or fragment must be identified so as to permit traceability between donor and recipient.

4. Regarding the invalidation of a product



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– in the case of invalidation of a tissue or organ (complete or partial), a deed of invalidation must be written.

5. Regarding surveillance

– Adverse effects or reactions occurring in transplantation patients and transplant rejection must be reported to Lusotransplante, which is charged with recording them and then communicating them to the Portuguese Transplantation Organisation (OPT).

C – Medicinal products

So as to facilitate the identification of medicinal products to which the legislation proposed herein applies, a conventional mark for them must be agreed upon, which all their packaging and/or labels must bear.

D – Plasma-derived Products

As to medicinal products derived from plasma:

1. Regarding Harvesting

The companies that hold a license for introducing such products into the market will be responsible for setting up the proper records (donor identification, harvest date, results of the control tests of the several harvests that yielded the totality of the plasma used to manufacture the medicinal product, etc.).

2. Regarding connected procedures

– such companies must abide by the legislation and norms in force in Portugal and in the European Union regarding the area of medicinal products.

3. Regarding the identification of the medicinal product

– by identification of the medicinal product is meant its trade mark, its international common designation (ICD), its batch number, and the name of the manufacturer.

4. Regarding (the) Recipient(s)

– the clinical record of the recipients of these medicinal products must bear the identification of the product, the amounts administered, and the beginning and end dates of administration.

– the hospital pharmacy must set up a file for each patient (or for each department) to whom was prescribed (or which has requested) a plasma-derived medicinal product, containing the name of the patient (or the name of the department), the name of the prescribing physician, the identification of the product in accordance with the description above, the date of the request, and the amount administered.



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C.2 – Other Human-origin Biological Medicinal Products and Biotechnological Medicinal Products

As to other biological medicinal products from human origin and from biotechnology:

1. Regarding the raw materials:

The safety of the raw materials used in the medicinal products is the responsibility of the companies holding a license to introduce them into the market. Thus, such companies must take every necessary measure to keep data records that permit at a later date the determination of causality in the case of any occurrence of adverse effects or reactions to these medicinal products.

2. Regarding connected procedures

– such companies must abide by the legislation and norms in force in Portugal and in the European Union regarding the area of medicinal products.

3. Regarding the identification of the medicinal product

– by identification of the medicinal product is meant its trade mark, its international common designation (ICD), its batch number, and the name of the manufacturer.

4. Regarding (the) Recipient(s)

– the clinical record of the recipients of these medicinal products must bear the product's trademark, its ICD, the name of the manufacturer and whenever possible the batch number, as well as the amounts administered and the beginning and end dates of administration.

D – Other Human-Origin therapeutic products not covered by points A, B and C

To any therapeutic product that contains material from human origin shall apply points 1, 2 and 4 of C.2, with the proper adjustments. The identification of the product must comply with the statutory rules according to which the product is classified.

VII – Conservation of the record archives and of the clinical histories

All records as well as clinical histories are to be conserved for a period of 50 years, since this is the period already set for the conservation of records on blood and components thereof.

VIII – Entities responsible for keeping archives of the records and clinical histories

A – On Blood and Components Thereof

1 – Records referring the donor, the harvesting, processing and conservation of the product must be kept in the institutions where the product was harvested and conserved.



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2 – The records containing data on the donor must be kept together with the clinical history, and also in a specific archive in the Immuno-haemotherapy Services.

3 – The records referring the name of the donor, the identification of the component (name, harvest batch number, and donor number), the amounts administered and the date of administration, must be forwarded periodically to the National Centre of Haemo-surveillance (to be created).

B – On human-origin biological products used in transplantation

1 – The records referring the donor, the harvesting, the conservation and processing of the material to be used as a transplant, as well as data on the recipient, must be kept in the Harvesting Unit or Tissue Bank, and be forwarded to Lusotransplante together with the clinical history to which they relate.

2 – When it is not possible to collect the data set forth in point 1.3 of "Data to be recorded", and the product is allotted to a transplantation, the statement referred, justifying the absence of data on the donor, must be attached to the clinical history of the recipient.

C – On Medicinal Products

1 – Records detailing the manner of obtaining the product, specifying the donors who originated the plasma used in the case of plasma-derived products, and the raw material in the case of other medicinal products, must be kept by the manufacturer, so that they may be consulted, if necessary.

2 – The records containing the identification of the recipient, the identification of the medicinal product, the amounts administered and the beginning and end dates of administration, must be filed together with the patients' clinical history, regardless of whether they received therapy as in-patients or as out-patients. If it is not possible, in the case of a private medical practice, to keep the clinical histories for the statutory period, those histories must be transferred to the health unit of the region where the health establishment is located.

3 – The records referring the name of the donor, the identification of the medicinal product, the amounts administered and the beginning and end dates of administration, must be forwarded periodically to the National Centre of Pharmacosurveillance.

IX – Recipient Card

Given the present impossibility of creating a specific card, we suggest that, when the Health User Card computer data network is created, some thought be given to the possibility of allotting some space on that card for registering the holder as a recipient of



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human-origin biological and biotechnological products. That record shall contain the name of the therapeutic product and the identification of the clinical history where that product has been entered.

Until using such a card is possible, the recipients of these products should bear a provisional card containing the data mentioned above.

By the presentation of these conclusions, the Work Group considers it has discharged the functions to which it was appointed.

Nevertheless, the Work Group wishes to stress that, while it is aware of the costs involved in the implantation of the surveillance system (creation and maintenance of computer products adequate to the storage and management of the data to be collected, recruiting and training the staff required for this activity, and so on), it feels certain that such a system will prove to be a benefit, bringing great advantages to Public Health.

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