



MISSION REPORT FOR ASSESSMENT OF THE IMPLEMENTATION OF THE ADOPTED LEGISLATION

1. *Twinning Contract references*

Mandatory Result 1

The overall Moldovan legislation related to transplant of human organs, tissues and cells is in compliance with EU and international standards and norms

A 1.1.1 Assessment of the implementation of the adopted legislation

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Beneficiary Administration Human Resources	Representatives from Transplant Agency, Ministry of Health, authorised hospitals
Outputs	Assessment report on the existing legislation including recommendations for further development elaborated
Benchmark	Good understanding of the existing legal environment shared by all project's partners
Planned timing	Month 2
Total planned duration of activity	5 WD
Time spent since the beginning	0 WD
Missions N°	1
Duration of current missions	5 WD
Mission	from: 24/02/2014 to: 28/02/2014

Context:

The activity of tissue transplantation (bones, corneas) started in the Republic of Moldova in the 1960s. Since 1982 and, after the completion of the first organ transplant, until the early 2000s, many transplants were conducted under the governance of the Decree of the Soviet Minister of Health of February 22 (1982) « The right of kidney procurement and preservation for transplant » and, then, under the governance of law n°473-XIV on human organs and tissues transplantation of 1999.

In 2002, the Republic of Moldova experienced a case, which deeply shocked the entire population, as well as the international community, when the media revealed the existence of an organ trafficking network active within its own healthcare institutions.

From this moment on, the public authorities decided to suspend the organs, tissues and cells procurement and transplantation activity, and to authorize its resumption only under the condition of creating a strict legal, medical and ethical framework.



Since then, a large number of texts have been adopted by the Parliament and approved by the Government in order to oversee the donation of elements and products of the human body and thus to regulate this activity endeavoring to develop standards of quality and safety for the protection of donors and transplant recipients.

Nowadays, the progressive relaunch of this activity constitutes a priority for the Government and particularly for the Ministry of Health, in order to enable the users of the health service of Moldova to benefit from this innovative and effective treatment.

In 2013 :

- 10 kidney and 3 liver transplantations were performed;
- 450 patients under dialysis;
- 39 patients were registered on the national waiting list (26 for kidney transplantation and 13 for liver).

Early 2014, one kidney transplantation from a deceased donor was performed and 1 liver transplantation from a living donor.

At present 4 establishments are authorized for organs procurement and 8 are authorized for the procurement of tissues. In the same time 1 establishment is authorized for organs transplantation and 8 for the transplant of tissues.

Only one bank is authorized for the preservation, processing and distribution of tissues (bones, femoral heads, valves, corneas, skin, placenta...).

As regards the activity of the allogeneic hematopoietic stem cell procurement and transplantation, it has not yet been authorized on the territory. There are however 2 centers (1 public and 1 private), no autologous transplantation has been performed yet.

After pointing these contextual elements, the Ist Chapter of this report is dedicated to the study of the existing legal framework compared to the guidelines covered by the European directives. The IInd Chapter draws up the problems and the possible ways of improvements for enabling a full and effective implementation in terms of European standards.

I – The legal framework governing the organs, tissues and cells procurement and transplantation activity or the implementation of the major principles derived from the European law.

The directive 2004/23/EC of the European parliament and the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (+ commission directives 2006/17/EC and 2006/86/EC) and the directive 2010/45/UE of the European parliament and the Council of July 7, 2010 on the standards of quality and safety of human organs intended for transplantation aims to reduce the risks and maximize the benefits of transplant activities. The Member States should implement an effective framework for quality and safety.

These two directives establish the rules aimed at ensuring the standards of quality and safety of organs, tissues and cells of human origin intended for transplantation into the human body, for ensuring a high level of protection of the human health (art.1).



This framework should be implemented and maintained throughout the chain ranging from donation to control, to characterization, to obtainment, to transportation up to transplantation (art.2).

In addition, the directives remind that the risk-benefit ratio and the evaluation of the potential donors are important elements of transplantation and that, as such, the role of the clinician is fundamental.

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The Parliament of the Republic of Moldova has ratified first of all the convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and of the additional protocol to the convention on the prohibition of cloning human beings (Law n° 1256-XV of July 19, 2002) and the additional protocol to the convention on human rights and biomedicine concerning transplantation of organs and tissues (Law n° 261 of December 6, 2007)

The founding act of the legal framework of Moldova concerning the procurement and transplantation is law n° 42-XVI of the Parliament of the Republic of Moldova of March 6, 2008 « On transplant of human organs, tissues and cells ».

In its field of application are included « all human organs, tissues and cells; **except** reproductive organs, embryonic or fetal tissues, cells and organs; blood and blood derivatives »

This text is currently being revised by the Parliament of the Republic of Moldova particularly for modifying its field of application and for including also the umbilical-cord blood, bone-marrow and peripheral blood hematopoietic stem cells.

As for Order n° 234 of March 24, 2011 of the Ministry of Health on the organization and conduct of the procurement and transplantation of human tissues, organs and cells, **technical requirements** concerning all these activities (donation, procurement, testing, processing, preservation, storage, distribution, coding and traceability, notification of serious adverse reactions and events occurred during their transplant) have been approved.

«Member states shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation (...) The framework for quality and safety shall provide for adoption and implementation of operating procedures (...)» Directive 2010/45/EU + Directive 2004/23/EC => currently being implemented

Those texts form the legal and regulatory framework for the transplant of all human organs, tissues and cells in Moldova.

Among the general principles, the law states that:

- ***“Protecting the dignity and character of a human being and guaranteeing to every person, without discrimination, respect for their integrity and for other fundamental rights and liberties concerning the transplantation of human organs, tissues and cells”;***



- “Performing transplants of human organs, tissues and cells from a live or deceased donor exclusively for the **therapeutic benefit** of the recipient when there are no efficient alternative therapeutic methods available”;
- “Observing **professional standards** and duties in any intervention in the field of transplanting human organs, tissues and cells”;
- “**Traceability** via guarantee of identification of organs, tissues and cells meant for transplantation within process of extracting, stocking and distribution from a donor to a recipient and vice versa”;
- “Protecting **personal rights** and freedoms and preventing the sale of human body parts”
- “Giving patient **fair access** to transplant services”.

Donation and transplant of organs, tissues and cells of human origin **shall not be the subject of a financial transaction. All financial profit from donating human organs, tissues and cells and promotion of the need for transplants are prohibited.**

“Altruism is an important factor in organ donations. To ensure the quality and safety of organs, organs transplantation programs should be founded on the principles of voluntary and unpaid donation” – Directive 2010/45/UE – Cons. 19 => **implemented in the legal framework**

“Member states shall prohibit advertising the need for or availability of, organs where such advertising is with a view to offering or seeking financial gain or comparable advantage” – Directive 2010/45/EU – article 13 + Directive 2004/23/EU – article 12 => **implemented in the legal framework**

However, the living donors may receive compensation, which should be limited strictly to the coverage of expenses and inconveniences (loss of revenues, medical actions...)

“ The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation” Directive 2010/45/UE – article 13 => **implemented in the legal framework**

According to international basis of legality of the penal law, Moldovan legislator provided that **trafficking** in human organs, tissues and cells qualifies as a **criminal offence and is punishable by the effective criminal legislation.**

→Article 158 in the version of Law n°270 of November 7, 2013, of the Penal Code of the Republic of Moldova about trafficking in organs, tissues and cells

This law also establishes the **Transplant Agency**, a public institution placed under the authority of the Ministry of Health and financed by the state, is responsible for the organization and surveillance of all transplant activities carried out on the national territory (art.4).



Placed under the authority of the Transplant Agency, the **Advisory council regulation** is responsible to provide a scientific opinion on the draft or normative acts of technical nature established by the Agency, to develop proposals regarding the allocation criteria, new transplantation activities, guidelines and protocols or ethical aspects.

→Decision n°386 of May 14, 2010 on establishment of the Transplant Agency and order 2010 on approval of the Advisory council regulation under the Transplant Agency

The law provides the **authorization of activities** and stipulates that all establishments (medical and health institutions) performing the activity of procurement, transplantation or preservation of organs, tissues and cells must be authorized in compliance with **criteria** approved by the Government, by the Ministry of Health on the proposal from the Transplant Agency. In particular, these establishments should submit an activity report (art. 9).

« Any activity in the field of transplants must be performed at the highest professional level and be in conformity/ with ethical standards » (article 8)

→Order n°234 of March 24, 2011 – « On the organization and conduct of the procurement and transplantation of human tissues, organs and cells »

«Members states shall ensure that procurement and transplantation take place in, or is carried out by, organizations that comply with the rules laid down in this directive ». **Directive 2010/45/EU - Article 5 and 9 => implemented in the legal framework**

« Member states shall ensure that procurement takes place in operating theatres, which are designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured » **Directive 2010/45/EU – article 5 et 6 => implemented in the legal framework**

«The transplantation centre shall verify before proceeding to transplantation that the organ and donor characterization are completed and recorded in accordance with article 7 and the annex and that the conditions of preservation and transport of shipped organs have been maintained » **Directive 2010/45/EU – article 9 => implemented in the legal framework**

The legislator provided the creation of a **national patient waiting list** for transplant, as well as a procedure of **organ allocation** according to the rules approved by the Order of the Ministry of Health.

→Order n°234 of March 24, 2011- « Rules for developing the waiting list / Common organ allocation rules », Order n°493 of June 16, 2011 on elaboration of kidney, liver and heart transplant waiting list and Order n°118 of February 8, 2013 on launching the automated information System Transplant (automated information system)

The deceased donors can be subject to procurement procedures only if the death was detected and confirmed according to criteria established by the Ministry of Health (art. 11):



- *"After irreversible cardiac/respiratory arrest, not susceptible of resuscitation, occurring to a person of normal or nearly normal temperature, the death must be confirmed within at least 5 minutes after the performance of all resuscitation measures, during which all tests must prove without a doubt that there is no blood circulation to the brain and to vital organs" ; AND*
- *"In the case of persons with irreversible changes in the vital centers of the brain, the death must be confirmed by specific tests (criteria) approved by the Ministry of healthcare, while the cardiac and respiratory function is maintained artificially".*

→Standardized clinical protocol of Ministry of Health of the Republic of Moldova: "Management of the potential brain-death donor" and "Brain death donor"

"The certification or the confirmation of death in accordance with national provisions before the procurement of organs from deceased persons and allocation of organs based on transparent, non-discriminatory and scientific criteria" Directive 2010/45/EU – Cons. 20 => **implemented in the legal framework**

Definition and diagnosis of brain death is currently being reviewed.

As to avoid any suspicions, the doctors that confirm the death of a potential donor **must be different** from those directly participating in the retrieval of an organ, tissues or cell; from those participating in subsequent transplant procedures; or from those responsible for the care of a potential recipient (art. 12).

With respect to the modalities of the consent for donation, the legislator of Moldova has opted for a presumed reinforced **consent** regime and in principle, the procurement is impossible if during his/her life the donor has expressed his/her opposition to organ donation.

Article 13 of the law stipulates that *"(1) Procurement is possible only based on the consent of the person before dying. (2) Procurement is prohibited in any form, when during their lifetime, the deceased opted against donation, by an act of refusal in holograph or in legal form. (3) When consent is absent, donation is possible only when the first degree relatives, the spouse or the legal representative of the deceased have not expressed a written refusal regarding donation. (4) Donation is possible without the consent of close relatives or of legal representatives, when no relative or legal representative, who could express the option regarding the donation, has presented themselves the legal declaration on the death and data on close relatives or legal representatives of the person are unavailable. (5) Organ, tissues and cells retrieved from a deceased donor in medical and legal cases shall be made upon the consent of the forensic/medical expert."*

"The procurement of organs shall be carried out only after all requirements relating to consent, authorization or absence of any abjection in force in the member state concerned have been met" Directive 2010/4EU– article 14 => **implemented in the legal framework**

In order to ensure the respect and dignity of the human being, the doctors, who carried out the removal of parts of the human body, are required to perform the **body restoration**.



As concerning **living donors**, the law of March 6, 2008 establishes the principle of subsidiarity. In fact, such procurements can be performed only when there are no compatible organs, tissues and cells from a deceased donor (art. 15) and only from adult persons with full legal capability when they have given their written, free, prior and express consent and only when the Independent Approval Commission has given authorization.

"Member states shall take all necessary measures to ensure the highest possible protection for living donor in order to fully guarantee the quality and safety of organs for transplantation.

Member state shall ensure that living donors are selected on the basis of their health and medical history, suitably qualified or trained and competent professionals. Such assessments may provide for the exclusion of persons whose donation could present unacceptable health risks.

Member state shall ensure that a register or record of the living donor is kept (...) and shall endeavor to carry out the follow-up of living donors (...)" Directive 2010/45/EU- article 15 => being implemented

This **Independent Approval Commission** is an independent authority which is not involved in the activity of the Transplant Agency. It's composed of representatives from the Expert Council of Ministry of Health: a psychologist, a psychiatrist, a representative from the ethics committee, and a representative from the Ministry of internal affairs specialized in issues of combating trafficking in human beings and a representative of the general prosecutor's office.

Its mission is to evaluate the legality and the motivation of donation procedure carrying out all necessary investigations concerning the donor and the recipient (information, risks and consequences of donation for his/her life...). The Commission has to verify that the donation has an altruistic character and is not the object of a financial transaction (art. 18).

→Decision n°1207 of December 27, 2010 on approval of the regulation, on organization and operation of the independent approval commission under the Ministry of Health and authorization criteria for the activities of procurement and transplantation and Order n°885 of November 18, 2011 approving the documents of the independent approval commission that consents or rejects procurement of organs, tissues and cells from living donors.

Protection of vulnerable people – The law provides that procurement from minors and from legally incapable adults is prohibited. In exceptional cases, the retrieval shall be authorized by the independent Approval commission, with the consent of the legal representative of the donor or of the guardianship authority if the donation process is performed in the interest of a person who is close relative first degree with the donor.

To meet the requirements linked to health safety and to avoid the risks of disease transmissions, the law establishes the principle of the clinical and biological selection of donors (art. 21) and stipulates also the authorization of establishments providing the processing, preservation and distribution of tissues and cells of human origin (art. 22).

→Cf. Technical requirements of Order n°234 of March 24, 2011



Also, to ensure **traceability** of all tissues and cells, the law entrusted the Transplant Agency with the obligation of establishing a **coding** system in order to be able to identify all tissues and cells stored in banking, as well as all donors by assigning them a unique identification code (art. 23).

« Member states shall ensure that all tissues establishments where activities of testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are undertaken have been accredited (...) by a competent authority (...) » **Directive 2004/23/EU – article 6 => implemented in the legal framework**

« Member state shall ensure that all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa (...) and ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it »

« (...) data required for full traceability is kept for a minimum of 30 years after donation » **Directive 2010/45/EU – article 10 + Directive 2004/23/UE – article 8 => being implemented**

The Transplant Agency is also responsible of the organization of inspections of all authorized establishments at least once a year and for the establishment of a **biovigilance** system enabling the identification, reporting and investigation of serious adverse events occurred during transplantation (Law no 42, art.6 and 7).

« Member states shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterization, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities » **Directive 2010/45/EU + Directive 2004/23/EU– article 11 => being implemented**

The law provides that this system is subject to the respect for **confidentiality** and **protection of data** collected during the activity according to the regulation concerning the protection of personal data (art. 25).

« Member states shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities (...) » **Directive 2010/45/EU – article 16 + Directive 2004/23/EU – article 14 => implemented in the legal framework but not in the current practice**

→Law n°33 of July 8, 2011 on personal data protection according to the directive 95/46/EC of the European Parliament and of the Council of October 24, 1995 on the protection of individuals with regard to the processing of personal data on the free movement of such data

It is important to underline that, in addition, the Government of the Republic of Moldova approved on October 9, 2012 (Decision n° 756) the **National Transplant Program for 2012-2016** that set the goals and specific objectives of the program and an action plan.



II– A legal framework, to be developed with a view to have a full and effective implementation of the European standards

Even if the European standards contained in the Directives were incorporated for the major part in the organic law of March 6, 2008 and in Order n° 234, the link between these 2 legal instruments, sometimes, seems to lack consistency: for example, the annex 3 to the technical requirements approved by the order of the Ministry of Health n°234 of March 24, 2011 fixed the selection criteria and laboratory tests required for donors of reproductive cells available gametes, while the gametes are excluded from the field of application of the law of March 6, 2008).

Although this recent legal framework includes the key points of the annexes of the European Directives, one could suggest a certain number of ways of improvement in view of the activity visit 1.1.1.1 « Assessment of the implementation of the adopted legislation ».

Concerning the organs:

- Donors, as well as persons subject to transplantation, should be the subject of a strict and organized monitoring;
- Informing the public about the existence of the national register of refusals should be done;
- Regarding the transportation and preservation, data enabling to ensure the traceability of organs should be the subject of established procedures and the role of coordinating bodies should be enhanced.

Moreover, although the use of organs to some extent raises the same issues as the use of tissues and cells, there are nevertheless important differences and the 2 subjects should be treated according to their specificity.

Directive 2004/23/CE is applicable, indeed, to the hematopoietic stem cells from peripheral blood, from the umbilical cord and from the bone marrow, as well as to the reproductive cells, to the fetal tissues and cells and to the adult and embryonic stem cells.

It, therefore, seems necessary to **provide a specific legal framework enabling the protection and regulation of these human body's products in order to ensure the same degree of protection.**

Legislative stipulations could also regulate **the use of surgical residues**, namely, tissues, cells and products of the human body removed on the occasion of a surgical intervention performed in the interest of the person, in order to provide donors at least information about the use and the purposes of products collected this way.

Specific legislative provisions should be especially adopted in order to regulate **the use of hematopoietic stem cells**, as well as the establishments or agencies ensuring the processing, the preservation, the distribution and the transfer, for autologous or allogeneic use, of tissues and their derivatives, as well as preparations of cell therapy in compliance with the guidelines of Directive 2004/23/EU.

As for law n° 138 of June 15, 2012 on reproductive health, it designates the legal framework of the medically assisted procreation, in force on the territory of the



Republic of Moldova, but does not say a word about the general principles of the voluntary and free donation.

The regulation of these germinal cells could, otherwise, be incorporated in the organic law no 42 of 6 March 2008 in order to establish a coherent framework with an equal protection level.

Finally, procedures and authorizations necessary for the protection of personal data should be formalized in collaboration with the competent Commission for Personal Data Protection established by law n° 133 on personal data protection.