DECISION no. 760 of July 1st 2009
on setting up a National Registry of Volunteer Donors of Hematopoietic Stem Cells and on approving the establishment of an activity financed entirely from own income

This decision has been effective since August 7th, 2012
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The text was updated using the legislative LEX EXPERT IT product, based on the amending normative acts, published in the Official Journal of Romania, Part I, until August 7th 2012.

Main act
#B*: Government Decision no. 760/2009*

Amending acts
#M1*: Government Decision no. 388/2011*
#M2*: Government Decision no. 753/2012*

*The amendments and additions taken from the above-mentioned normative acts are written in italics. Each amendment or addition is preceded by the symbol of the normative act that generated the respective amendment or addition, in the form of **#M1**, **#M2** etc.*

#CIN
NOTE:
*The title of the normative act was amended according to art. I point 1 of Government Decision no. 388/2011 (**#M1**).*

#B
Pursuant to art. 108 of the republished Constitution of Romania and to art. 15 paragraph (2) of Law no. 95/2006 on healthcare reform, with subsequent amendments and additions,

the Government of Romania hereby adopts the following decision.

CHAPTER I
General provisions

ART. 1
The National Registry of Volunteer Donors of Hematopoietic Stem Cells, hereinafter called the Registry, is set up as public institution with legal personality, subordinated to the Ministry of Health, headquartered in Bucharest, 2 – 8 Constantin Caracas, district 1.

#M2

ART. 1^1
The Registry shall be the institution responsible for:

a) processing national or international requests for using hematopoietic stem cells from unrelated donors;
b) issuing the permit referred to in art. 148 paragraph (10) of Law no. 95/2006 on healthcare reform, with subsequent amendments and additions;
c) coordinating and auditing the activities of recruitment, testing and donation of hematopoietic stem cells from unrelated donors;
d) implementing the single coding and labeling system, in line with the European requirements of coding the activity of donating hematopoietic stem cells from unrelated donors for transplant purposes.

#M1

ART. 2

The Registry's main activities shall be:
a) the methodological coordination of the recruitment, testing and donation of hematopoietic stem cells from unrelated donors;
b) creating and managing an IT database, on the territory of Romania, to include the individuals who gave their consent to donate stem cells, as well as their personal, medical and histocompatibility data;
#M2
c) identifying compatible donors of hematopoietic stem cells in their own database and in international databases;
#M1
d) mandatory interconnection with similar international bodies;
e) research on stem cell transplant;
#M2
f) developing the national standards in accordance with the European regulations in force, with the standards of the World Marrow Donors Association, hereinafter called WMDA, of the European Federation for Immunogenetics, hereinafter called EFI, of the Joint Commission on Accreditation, hereinafter called JCA, and with the relevant recommendations of the World Health Organization;
g) promoting the donation of hematopoietic stem cells.

#M1

ART. 3

The Ministry of Health is the regulatory authority for the activities related to the donation of hematopoietic stem cells from unrelated donors.

#M1

ART. 4

(1) The Registry shall be financed entirely from the State budget, through the budget of the Ministry of Health.
#M2
(2) The establishment of an activity financed entirely from own income, namely the activity of providing, upon request, the information on identifying compatible donors of hematopoietic stem

cells, hematopoietic stem cells and additional hematopoietic therapeutic products to similar structures and healthcare units outside Romania is hereby approved.

#M1

(3) The activity referred to in paragraph (2) falls under the "Healthcare" budget chapter.

(4) The own income for funding the activity referred to in paragraph (2) shall come from:

#M2

a) the fee for providing, upon request, the information on identifying compatible donors of hematopoietic stem cells, hematopoietic stem cells and additional hematopoietic therapeutic products to similar structures and healthcare units outside Romania;

#M1

b) distributing statistical data and information on the transplant of hematopoietic stem cells and producing statistical papers in addition to those included in the approved annual plan;

c) funds resulting from international collaborations, programs or projects;

d) legally collected interest on available funds and deposits set up from the income generated by the activities referred to in paragraph (2);

e) donations and sponsoring;

#M2

f) scientific research activities.

#M1

(5) The income generated by the activity referred to in paragraph (2) shall be used to cover the expenses related to the activity financed entirely from own income and to further develop this activity.

(6) In case of expenses overlapping with the activities financed from the State budget, the funds for the activities referred to in paragraph (2) shall be established based on distribution keys, set by the institution management.

(7) The income and expense budget for the activity referred to in paragraph (2) shall be approved when the institution's budget is approved, the execution of cash accounts shall be done through the State Treasury, according to the legal provisions in force, and the execution of cash accounts shall be reported in accordance with the instructions issued by the Ministry of Public Finance.

(8) The annual surplus resulting from the execution of the income and expense budget for the activity referred to in paragraph (2) shall be carried forward to the following year and shall be used for the same purposes.

(9) In case the activity financed entirely from own income referred to in paragraph (2) does not have sufficient funds at the time of its establishment, the main authorizing officer, based on thoroughly substantiated documentation, may grant interest-free loans from its own budget, based on agreements, according to the law.

#M2

ART. 4^1

In order to interconnect with similar international institutions, as well as to obtain the accreditation of the Registry from WMDA and of the HLA laboratories from EFI, the Registry shall pay the following annual taxes and fees:

a) WMDA membership fee;

b) membership fee to Europdonor – Bone Marrow Donors Worldwide, hereinafter called BMDW;

c) membership fee to the European Group for Blood and Marrow Transplant, hereinafter called EBMT;
d) WMDA and EFI accreditation fee.

#M1

ART. 5

(1) The Registry shall operate in line with the confidentiality and anonymity principles, according to the law.
(2) The personal data of hematopoietic stem cell donors shall be processed only for the purposes for which they were collected and in accordance with the provisions of Law no. 677/2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data, with subsequent amendments and additions.
#M2
(3) For the purposes of this decision, the following personal data of hematopoietic stem cell donors shall be subject to the legal processing by the Registry, according to the provisions of paragraph (2):
a) name and surname;
b) personal numerical code;
d) height;
e) weight;
g) home address;
h) phone number;
i) e-mail address;
j) blood type and Rh;
k) data reflecting the histocompatibility profile, namely: class I HLA (HLA-A, HLA-B, HLA-C) and class II HLA (HLA-DR, HLA-DQ, HLA-DP) genes, with the matching alleles;
l) data reflecting the presence of infectious markers for infections with the human immunodeficiency virus (HIV), the Human T-cell lymphotropic virus I and II, hepatitis B virus, hepatitis C virus, cytomegalovirus (CMV), Epstein Barr virus, toxoplasmosis and Treponema pallidum (syphilis).

#M1

ART. 6

(1) The Registry shall operate without imposing any constraints in order to obtain donations of hematopoietic stem cells for therapeutic purposes.
#B
(2) The Registry shall take appropriate technical and organizational measures to protect personal data against accidental or illegal destruction, loss, modification, disclosure or unauthorized access, as well as against any other forms of illegal processing.
#M2
(3) During its operation, the Registry may take a liability insurance policy, to be paid from the State budget through the Ministry of Health budget, without exceeding the annually approved funds.

#B

CHAPTER II
Organization and functioning of the National Registry of Volunteer Donors of Hematopoietic Stem Cells

#M1

ART. 7

The Registry shall have mainly the following tasks:

a) to create and manage the secured digital database of volunteer donors of hematopoietic stem cells, in line with the provisions of Law no. 506/2004 on processing personal data and protecting the privacy in the sector of electronic communications, with subsequent amendments and additions;

b) to interconnect with the structures operating in this field in order to establish an efficient communication link at national level;

c) to implement the quality management system in its own structures

d) to regularly check the working standards of its structures;

e) to submit campaigns promoting the donation of hematopoietic stem cells for therapeutic purposes for the approval of the Ministry of Health;

f) to promote the activity of donating hematopoietic stem cells;

g) to implement and check the observance of quality and security standards during the recruitment and testing of unrelated donors of hematopoietic stem cells, as well as during the donation of hematopoietic stem cells, according to the relevant European standards;

h) to collect and review the most recent data in the field in order to monitor the risks that may have a direct impact on the quality of the hematopoietic stem cells donation;

i) to provide, upon request, specialized consultancy and information about the donation of hematopoietic stem cells to the institutions operating in this field;

j) to submit draft normative acts in the relevant field to the Ministry of Health;

k) to interconnect with similar international institutions in order to find compatible donors;

l) to draft and implement, also in cooperation with specialized institution from the country and from abroad, professional education and training programs for the healthcare staff involved in the activities of recruitment, testing and donation of hematopoietic stem cells;

m) to cooperate with the national authority responsible for the health security of human products for therapeutic use;

n) to initiate, conduct, coordinate or approve, as needed, research activities in the field;

#M2

o) to draft the national standards of the Registry and submit them to the Ministry of Health for approval, by order;

#M1

p) to define and supervise the measures for the traceability of hematopoietic stem cells donated for therapeutic purposes from donor to recipient and vice versa, which are kept for at least 30 years in the Registry's database;

q) to submit activity reports to the Ministry of Health quarterly or annually or whenever necessary;

r) to reimburse the expenses for the national or international transport of compatible hematopoietic stem cells to the healthcare unit where the patient is located;

s) to reimburse the expenses for the services of searching in other registries;

t) to reimburse the expenses with the transport made upon its request for the selected donor;
u) to exercise other relevant duties, according to the law;
#M2
v) to methodologically coordinate the recruitment, testing and donation of hematopoietic stem cells from unrelated donors and to conduct the audit of the activities it coordinates, in line with the WMDA standards;
w) to make sure the national standards are observed and to endorse all official documents regarding its WMDA accreditation;
x) to implement the Single coding and labeling system (ISBT 128) in line with the European coding requirements regarding the donation for transplant of hematopoietic stem cell from unrelated donors.

#M2

ART. 7^1

In order to conduct the activity referred to in art. 7 letter (g), the Registry shall obtain the accreditation from the bodies certifying the quality and security standards, according to the relevant European standards, namely:
a) the quality management system standards;
b) the standards for the information security management system.

#B

ART. 8

(1) The Registry is managed by a general manager appointed through competition, by order of the Minister of Health.
(2) The General Manager is a tertiary authorizing officer and represents the Registry in the relations with the other public authorities, with legal entities and natural persons from the country and from abroad, as well as in court.
#M1
(3) The financial-accounting activity is conducted by a financial-accounting manager, appointed through competition, by order of the Minister of Health.
(4) Until the general manager and financial-accounting manager positions are filled through competition, the persons referred to in paragraphs (1) and (3) shall be temporarily appointed by order of the Minister of Health, according to the legal provisions.

#M2

ART. 9

(1) The recruitment, testing and donation activities shall be performed in line with the provisions of Law no. 95/2006, with subsequent amendments and additions, as well as with the WMDA standards, as follows:
a) the activity of recruitment through the regional transfusion centers and the healthcare units designated by Minister of Health order;
b) the activities of testing for blood type and Rh, virusological testing and histocompatibility testing through the laboratories accredited according to the law and designated by Minister of Health order;

c) the activity of harvesting hematopoietic stem cells through the harvesting centers accredited according to the law, designated by Minister of Health order.
(2) The activities of recruitment, testing and donation shall be performed in accordance with the standard operation protocols and the forms drafted by the Registry, endorsed by the Scientific Committee and subject to approval by Minister of Health order.
(2^1) The national standards of the Registry, the standard operation protocols and the forms are mandatory for all healthcare units involved in the activities of recruitment, testing and donation of hematopoietic stem cells.
#M1
(3) In order to comply with the tasks referred to in art. 7, the Registry may sign memorandum of understanding and/or service provision agreements with third parties, in accordance with the law.
#M1

ART. 10 *** Repealed
ART. 11 *** Repealed

#M2

ART. 12

(1) The Registry shall have its own Scientific Committee, made of six members who are prominent personalities in the field of testing, donating and transplanting hematopoietic stem cells, as well as the general manager of the Registry.
#M1
(2) The nominal composition of the Scientific Committee shall be set by Minister of Health order, upon proposal of the Registry.
(3) The General Manager of the Registry shall be a legitimate member of the Scientific Council.
#M2
(4) The Scientific Council is run by a chairperson, appointed among its members, with a six-month mandate.
#M1
(5) The tasks of the Scientific Council shall be set in the Registry's organization and functioning rules.
#B

ART. 13

(1) The Registry shall operate with a number of maximum 40 positions, filled by redistribution from the units subordinated to the Ministry of Health, financed entirely from the State budget.
(2) The Registry personnel shall consist of contracted personnel, hired on positions financed entirely from the State Budget.
#M1

ART. 14 *** Repealed

#M1

ART. 15

The measures of inspection and control regarding the health quality and security in the field of recruitment, testing and donation of hematopoietic stem cells shall be the duty of the national authority responsible for the health security of human products for therapeutic use, according to the law.

#B

CHAPTER III
Final provisions

#M1

ART. 16

(1) The organizational structure of the Registry and its organization and functioning rules shall be approved by Minister of Health order.

#B

(2) The entire stem cell donation procedure shall be approved by Minister of Health order, within 60 days from the entry into force of this decision.

ART. 17

Annex no. 2 “List of legally established units under the subordination, authority or coordination of the Minister of Health”, letter A “Units subordinated to the Ministry of Health”, point I “Units financed entirely from the State budget”, to Government Decisions no. 1.718/2008*) on the organization and functioning of the Ministry of Health, published in the Official Journal of Romania, Part I, no. 5 of January 6th 2009, with subsequent amendments and additions, shall be amended and added as follows:

1. A new point, point 15, shall be introduced after point 14, with the following content:

“15. The National Registry of Stem Cell Donors”.

2. The note shall be amended and shall have the following content:

“The maximum number of positions in the units referred to at points 1 - 15 is 8,204, of which:

– Tichilesti Hospital (leper hospital) – 28;

– resident doctors with tenure – 345.”

#CIN

*) Government Decision no. 1718/2008 was repealed by Government Decision no. 144/2010.

#B

ART. 18

This decision shall enter into force 30 days from the date of its publication in the Official Journal of Romania, Part I.