

On approval of the Rules for searching and activating a donor of hematopoietic stem cells, including from international registries, and transporting hematopoietic stem cells to the recipient

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 9, 2020 No. ҚР ДСМ-119/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 12, 2020 No. 21408

Unofficial translation

In accordance with clause 2 of article 215 Of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Health Care System", I HEREBY ORDER:

- 1. To approve the Rules for searching and activating a donor of hematopoietic stem cells, including from international registries, and transporting hematopoietic stem cells to the recipient in accordance with Appendix to this order.
- 2. The Department for Organization of Medical Care of the Ministry of Health of the Republic of Kazakhstan, in accordance with the procedure, established by law, shall ensure:
- 1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;
- 2) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;
- 3) within ten working days after the state registration of this order, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan, of information about implementation of activities, stipulated by subclauses 1), 2) of this clause.
- 4. Control over execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.
- 5. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

Minister of Healthcare of the Republic of Kazakhstan

A. Tsoy

Appendix to the order Minister of Healthcare of the Republic of Kazakhstan dated October 9, 2020 No. ҚР ДСМ-119/2020 Rules for searching and activating a donor of hematopoietic stem cells, including from international registries, and transporting hematopoietic stem cells to the recipient

Chapter 1. General Provisions

- 1. The Rules for searching and activating a donor of hematopoietic stem cells, including from international registries, and transporting hematopoietic stem cells to the recipient have been developed in accordance with clause 2 of article 215 Of the Code of the Republic of Kazakhstan "On Public Health and Health Care System" and shall determine the procedure for searching and activating a donor of hematopoietic stem cells (hereinafter referred to as the HSC), including from international registers, and transporting HSC to the recipient.
 - 2. The following basic concepts are used in these Rules:
- 1) activating procedure for obtaining repeated consent of the HSC donor for donation, as well as for conducting a control confirmatory tissue typing;
- 2) conditioning a method of therapy using high-dose chemotherapy or radiation therapy to prepare the recipient for transplantation of hematopoietic stem cells;
- 3) applicant (customer) an individual or a legal entity licensed for medical activities in "Transplantology", searching for a compatible donor, as well as sending a request for activation of an HSC donor for the purpose of transplantation;
- 4) information database of the Register information about phenotypes of a potential HSC donor;
- 5) phenotype a set of characteristics inherent in an individual, mediated by external factors, which is formed on the basis of a genotype (a set of genes of a particular organism).
- 3. Information about phenotypes of the bone marrow donors of the Republic of Kazakhstan shall be placed on the information platform "Bone Marrow Donors Search".
- 4. Searching and activating an HSC donor from the Register of Bone Marrow Donors (hereinafter referred to as the Register) and (or) the World Marrow Donors Association (hereinafter referred to as the association) for the citizens of the Republic of Kazakhstan shall be carried out within the framework of the guaranteed volume of free medical care.
- 5. Loss of documents or other media containing information about HSC donors, as well as their unlawful change by persons who have access to this information in connection with their official activities, shall be prohibited.

Chapter 2. The procedure for searching and activating of HSC donors from the Register, including from the international registers, and transporting HSC to the recipient

- 6. the search of a matched HSC donor in the information database of the Register and the association shall be carried out based on the principle of histocompatibility.
- 7. The application for the search shall be formed by the customer, who has an access to the information database of the Register and (or) the association.
- 8. If the search result is positive about the presence of a matched HSC donor in the Registry, an application shall be submitted for the search and activation of the donor for the purpose of transplantation.
- 9. The work on searching and activating a donor from the register shall be carried out within the period of up to two months from the date of receipt of the application.

Upon completion of work, the customer shall be notified about the results thereof.

If it is necessary to obtain additional information about the location of the HSC donor or his contact details, the search period shall be extended, which is communicated to the customer.

- 10. Search in the information base of the association shall be carried out in case of a negative search result for a matched HSC donor from the Register.
- 11. An application for the search for an HSC donor from an association for the purpose of transplantation to a recipient a citizen of the Republic of Kazakhstan shall be carried out by the customer independently.
- 12. Services of the association shall be paid by the customer according to the issued pro-forma invoices.
- 13. Donor activating shall be carried out by obtaining verbal confirmation of consent for donation of hematopoietic stem cells (hereinafter referred to as the HSC) and repeated (control) phenotype study at five loci (HLA-A, HLA-B, HLA-C, HLA-DRB1, HLA-DQB1) to allelic level (4 digits after the letter designation) in order to confirm compatibility with the recipient phenotype.
- 14. The donor's medical examination shall be carried out according to the clinical protocol for the examination of bone marrow donors for unrelated allogeneic transplantation, approved by the Republican Center for Health Development.
- 15. Terms for conditioning of the recipient, donation and transplantation of HSC shall be established by the customer.
- 16. Activating, as well as organizing the arrival of the HSC donor for donation shall be carried out by the Register.
 - 17. HSC shall be transported as a native or cryo preserved product.
- 18. The storage temperature and transport time of native HSCs shall be set by the customer.
- 19. When transporting cryo-preserved HSCs, a transport system shall be used to ensure the preset storage temperature.
- 20. When transporting the HSC, safety measures should be followed to prevent tipping, overturning, product irradiation.

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21. The customer shall organize the HSC transportation to the recipient.