



On approval of the rules for interaction on contract fractionation

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DSM-187/2020 dated November 9, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 10, 2020 under No. 21617

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Pursuant to sub-paragraph 54 of Article 7 of the Code of the Republic of Kazakhstan of July 7, 2020 “On Public Health and the Health Care System”, **I HEREBY ORDER:**

1. That the attached rules for interaction on contract fractionation shall be approved.
2. That Order of Minister of Healthcare and Social Development of the Republic of Kazakhstan No. 419 dated May 29, 2015 “On Approval of Rules for Interaction on Contract Fractionation” shall be deemed to have lost force (registered with the Register of State Registration of Regulatory Legal Acts under No. 11542, published on July 2, 2015 in Adilet, the information and legal system).
3. That in obedience to the procedure established by the legislation of the Republic of Kazakhstan, the Department of Drug Policy of the Ministry of Healthcare of the Republic of Kazakhstan shall:
 - 1) ensure the state registration hereof with the Ministry of Justice of the Republic of Kazakhstan;
 - 2) place this order on the web-site of the Ministry of Healthcare of the Republic of Kazakhstan;
 - 3) within ten working days from the date of state registration hereof with the Ministry of Justice of the Republic of Kazakhstan, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan the information on fulfillment of actions stipulated by sub-paragraphs 1) and 2) of this paragraph.
4. The supervising Vice-Minister of Healthcare of the Republic of Kazakhstan shall be charged with control over execution hereof.
5. This order shall be put into effect ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Annex to order
of the Minister of Healthcare
of the Republic of Kazakhstan
No. KR DSM-187/2020
dated November 9, 2020

Rules for interaction on contract fractionation

Chapter 1. General provisions

1. These rules for interaction on contract fractionation (hereinafter - Rules) haven been developed in conformity with sub-paragraph 54) of Article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 “On Public Health and Healthcare System of the Republic of Kazakhstan” (hereinafter referred to as the Code) and determine the procedure for interaction of healthcare organisations on contract fractionation.

2. The following concepts shall eb used in these Rules:

1) contract fractionation - direction of blood components, procured in the state health care organizations, carrying out activities in the field of blood service of the Republic of Kazakhstan, abroad for production of plasma blood products in factories of foreign manufacturers in order to provide the population of the Republic of Kazakhstan with blood products;

2) plasma blood products - products containing biological substances obtained from the processing of blood plasma;

3) single distributor - a legal entity carrying out activities within the guaranteed scope of free medical care and (or) within the compulsory social health insurance system in compliance with Article 247 of the Code (hereinafter referred to as the Single Distributor);

4) the main plasma procurer shall be a republican state health care organization carrying out activity in the sphere of blood service of the Republic of Kazakhstan.

Chapter 2: Interaction procedures for contract fractionation

3. Interaction for contract fractionation shall be provided by the following organisations:

1) public health organisations carrying out blood service activities that are plasma procurers;

2) a single distributor;

3) a plant-producer of plasma blood products providing contract fractionation service (hereinafter referred to as fractionator).

4. Plasma procurers shall send to the main plasma procurer for fractionation information about planned volumes of plasma procurement for the forthcoming three-year period by the first of December of the year preceding the year of conclusion of the long-term contract.

5. By the first of January of the current year, the main plasma procurer shall send to the Single Distributor information about the volumes of plasma to be procured for the subsequent production of plasma blood products for the forthcoming three-year period and in planning plasma procurement shall be based on the plasma procurers' capabilities.

6. Prior to bidding for the procurement of plasma blood products under contract fractionation, the prospective fractionator shall conduct a preliminary assessment of the terms

and conditions of the procurers in order to gain an understanding of the capabilities of the procurer.

7. The Single Distributor shall conclude a long-term contract for contract fractionation prior to the first of June of the current year in accordance with the procedure for organising and conducting the procurement of medicines, medical devices and specialised medical products within the guaranteed volume of free medical care and (or) within the mandatory social health insurance system, pharmaceutical services approved in accordance with sub-paragraph 3 of Article 6 of the Code.

8. Formation of demand for procurement of plasma blood products in excess of contractual fractionation shall be carried out with the account taken for the volume of plasma blood products produced and supplied under contractual fractionation.

9. By the first of July of the current year, the fractionator determined by the terms of the long-term contract with the Single Distributor shall work to identify plasma procurers from among the blood service organisations of the Republic of Kazakhstan.

10. The fractionator determined by the terms of the long-term contract with the Single Distributor shall organize assessment of conditions of plasma procurement and storage before the first of August of the current year.

11. After passing the assessment of conditions of plasma procurement and storage, the Procurer shall conclude a contract for plasma supply with the fractionator determined by the terms of the long-term contract with the Single Distributor.