Rwanda

Ministerial Order determining Blood Components which may be Sold and the Applicaple Procedure Thereof

Ministerial Order 1 of 2021

Legislation as at 17 May 2021

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[This is the version of this document from 17 May 2021.]

The Minister of Health;

Pursuant to the Constitution of the Republic of Rwanda of 2003 revised in 2015, especially in Articles 121, 122 and 176;

Pursuant to Law nº 53/2018 of 13/8/2018 modifying Law nº 04/2010 of 16/4/2010 regulating therapeutic, educational and scientific utilisation of organs and products of the human body, especially in Article 2;

After consideration and approval by the Cabinet, in its meeting of 14/04/2021;

ORDERS:

Article One – Purpose of this Order

This Order determines the blood components which may be sold and the applicable procedure thereof.

Article 2 – Definitions

In this Order, the following terms have the following meanings:

1° **blood components**: major blood components including plasma, platelets, red blood cells and white blood cells;

2° **plasma**: a light-yellow liquid part of blood that remains after red blood cells, white blood cells, platelets and other cellular components are removed from blood. It is the most important component of human blood, comprising about fifty-five percent (55%) and contains water, salts, enzymes, antibodies and other proteins;

3° **plasma fractionator**: manufacturing plant that performs plasma fractionation;

4° **Minister**: Minister in charge of Health;

5° **Institution**: The public institution in charge of processing blood components.

Article 3 – Blood components to be sold

Plasma is the blood component to be sold.

Article 4 – Quality requirements

The organ in charge for regulation of biological products determines quality requirements of plasma for sale.

Article 5 – Selling procedure

A plasma fractionator writes to the Institution expressing the interest to buy plasma.

The Institution assesses the request referred to under Paragraph One of this Article and accepts or rejects the intention of plasma fractionator to buy plasma.

The plasma fractionator assesses if plasma comply with the needed quality.

If the plasma fractionator finds that the plasma complies with the required quality, it concludes a collaboration agreement with the Institution.

Article 6 – Report on the quantity of blood collected and plasma extracted

The Institution submits to the Minister a written report indicating the quantity of blood collected, the quantity of plasma extracted, the quantity of plasma needed by health facilities and the excess plasma.

After analysis of the written report referred to in Paragraph One of this Article, the Minister authorizes the Institution to sell the excess plasma.

Article 7 – Authorisation to buy plasma and certificate to export plasma

The institution issues to a plasma fractionator an authorisation to buy the plasma for one (1) year which may be renewed upon agreement of both parties.

The Institution applies in writing for a certificate of export to the organ in charge of regulation of biological products.

Article 8 – Cost of plasma

The cost of plasma cannot be less than fifty United States Dollars (USD 50) per liter.

The price referred to in Paragraph One of this Article, is reviewed every year after consultations between the Ministry in charge of health and the plasma fractionator.

Article 9 – Repealing provision

All prior provisions contrary to this Order are repealed.

Article 10 – Commencement

This Order comes into force on the date of its publication in the Official *Gazette* of the Republic of Rwanda.