Prime Minister's Decree No. (2603) of 2021
on
Issuing the Executive Regulation of the Law of Regulating Blood operations and plasma collection for manufacturing and exportation of its derivatives
Promulgated by Law No. (8) of 2021

Prime Minister

Having perused the constitution;

- Penalties Law;
- Law of Criminal Procedures;
- Civil Law;
- Law No. (367) of 1954 on Organizing the Profession of Medicinal Chemistry, Bacteriology and Pathology; and Organizing Medical Diagnostic Laboratories, Scientific Research Laboratories, Biopharmaceutical Laboratories;
- Law No. (415) of 1954 on Medical Profession Practice;
- Law No. (127) of 1955 on Pharmacy Profession Practice;
- Law No. (2) of 1957 on Standardization;
- Law No. (21) of 1958 on Organizing and Encouraging Industry in the Egyptian Territory;
- Law No. (59) of 1960 on Regulating the Work of the Ionizing Radiation and Preventing its Dangers;
- Law No. (113) of 1962 on Reorganizing Importation, Manufacturing and Trading of Drugs, Medical and Chemical Devices;
- Law No. (118) of 1975 on Import and Export;
- Law No. (57) of 1979 on Establishing a Military Medical Academy of the Armed Forces;
- Law No. (51) of 1981 on Regulating Medical Facilities;
- Law No. (13) of 1983 on the Federation of Medical Professions Syndicates;
- Law of Public Business Sector Companies promulgated by Law No. (203) of 1991;
- Law of Civil and Private Universities promulgated by Law No. (12) of 2009;
- Law No. (5) of 2010 on Regulating Human Organ Transplantation;
- Law of Facilitating of Granting of Licenses for Industrial Facilities Promulgated by Law No. (15) of 2017;
- Law on Regulating Advertising of Health Products and Services Promulgated by Law No. (206) of 2017;
- Law of Comprehensive Health Insurance promulgated by Law No. (2) of 2018;
- Law of Regulating the Work in University Hospitals Promulgated by Law No. (19) of 2018;
- Law of the Public Authority for Industrial Development Promulgated by Law No. (95) of 2018;
- Law of Consumer Protection promulgated by Law No. (181) of 2018;
- Law of Regulating Contracts Concluded by Public Bodies Promulgated by Law No. (182) of 2018;
- Law on establishing the Egyptian Authority for Unified Procurement and, Medical Supply, Administration of Medical Technology and Egyptian Drug Authority Promulgated by Law No. (151) of 2019;
- Law of Personal Data Protection Promulgated by Law No. (151) of 2020;

- Law on Regulating Blood operations and plasma collection for manufacturing and exportation of its derivatives Promulgated by Law No. (8) of 2021;
- Executive regulations of the law of Establishing the Egyptian Authority for Unified Procurement and Medical Supply, Administration of Medical Technology and the Egyptian Drug Authority issued by Law No. (151) of 2019 Promulgated by Prime Minister's Decree No. (777) of 2020; and
Material presented by the Minister of Health and Population.

Has decided:

(Article One)

The provisions of the accompanying executive regulations regarding the law of regulating Blood operations and plasma collection for manufacturing and exportation of its derivatives promulgated by law No. (8) of 2021, shall be implemented.

(Article Two)

This DECREE shall be published in the 'Official Gazette' and shall come into effect from the day following its publication therein.

Prime Minister

(Dr. /Mostafa Kamal Madbouly)

Issued the Presidency of the Council of Ministers on Safar 29th, 1440 A.H.

(Corresponding to Oct. 6th, 2019 A.D.)

The executive regulations on the law of regulating Blood operations and plasma collection for manufacturing and exportation of its derivatives

(Chapter One)

Definitions:

(Article One)

For the purpose of implementing the provisions of this regulation, the definitions contained in the law of regulating Blood operations and plasma collection for manufacturing and exportation of its derivatives referred to shall have the same meaning as intended. In applying the provisions of these regulations, the following words and expressions shall have the meaning indicated next to each of them:

Law: It refers to the Law on Regulating Blood operations and plasma collection for manufacturing and exportation of its derivatives Promulgated by Law No. (8) of 2021.

National Standards: They refer to the Followed standards issued by national blood transfusion services in the competent ministry.

Blood Operations Center: It is every licensed blood bank in accordance with the controls set by the competent ministry and provide blood and its derivatives to patients. It is divided into:

1. **Blood Collection Operations Center:** It is the place in which the blood and its derivatives are donated, preserved, dispensed, blood derivatives are separated and the necessary tests for blood transfusion are carried out in accordance with the national standards.

2. **Blood Storage Operations Center:** It is the place in which the blood and its derivatives are preserved, dispensed them and conducted the necessary tests for blood transfusion are carried out, provided that the blood collection operations center shall provide safe blood obtained from the Blood Storage Operations Center, in accordance with the national standards.

3. **Blood Plasma Collection Unit for Therapeutic purpose:** It is the place in which The donated plasma for therapeutic purpose is preserved, preserved, dispensed and where the necessary tests are conducted, in accordance with the national standards.

Blood Derivatives: They are the Components which are separated, preserved from the blood and dispensed in the Blood Operations Center in accordance with the national standards.

Intermediate Plasma Derivatives: They are one of the plasma derivatives that are partially separated for further processing to bulk and finished products (bulks) and finished products.

Finished Plasma Derivatives product: They are biological products derived from blood plasma in finished pharmaceutical form.

Laboratory Serological Tests: They are tests conducted on the blood units and its derivatives after donation in accordance with the provisions of the regulations herein and international and national standards.

Factory: It refers to the factory whose main scope is manufacturing plasma derivatives for the purposes of the pharmaceutical industry. It has the right to purchase the plasma from the licensed plasma collection center for manufacturing or from one of the companies whose main

tasks is selling, plasma exportation for manufacturing then recovery, exporting and importing plasma.

Controlling Share: It refers to possession of fifty percent or more of the company's capital, the ability to appoint the majority of the members of the board of directors or controlling in any way the decisions issued by its board of directors or its general assemblies.

Sealed Customs Release: It refers to granting an initial releasing to the shipment subjecting to be sealed by the Egyptian Drug Authority to allow of receiving the shipments in preparation for final releasing in accordance with the regulating rules of the Egyptian Drug Authority.

(Chapter TWO)

Regulating Blood Operations

(Article Two)

A request for licensing a Blood Operations Center shall be submitted to the relevant department in the competent ministry on the form designated for this purpose. The request shall be signed by the license applicant or his legal representative and it shall contain the details of the center manager, his name, title, nationality and place of residence. The following documents shall be attached:

1. An official extract of the qualification certificates of the center director, as follows:

a) Bachelor of Medicine and Surgery, Master's degree, Diploma in Clinical Pathology, Transfusion Medicine or Transfusion Fellowship, in addition to an experience certificate for one year for PhD holders, two years for master's degree holders and three years for the diploma holders, provided that the experience certificate shall be approved by the administration concerned in the relevant ministry.

In the case of the license to be issued for a government authority, an experience certificate for the center director in the field of blood transfusion for at least seven years shall be sufficient, provided that the certificate shall be approved by the relevant department in the competent ministry. A decision specifying the controls and conditions for that experience, shall be issued by the competent minister.

b) An official extract of the license to practice profession issued by the competent ministry.

c) A copy of the national ID card.

2. A sketch showing the location of the Blood Operations Center and the distribution of its spaces, signed and approved.

3. The special form designated to indicate the hospital's capacity and its available medical specialties (if the center is within a hospital).

4. A statement of the work team names at the Blood Operations Center and their qualifications.

5. A statement of the Blood Operations Center's equipment.

6. Submitting the documents indicating the method of waste disposal.

It shall be prohibited for the same person to license more than two Blood Operations Centers, in the same governorate, with a maximum of three governorates.

(Article three)

The Blood Operations Center license shall be issued according to the following procedures:

1. The request shall be examined in the terms of fulfilling the documents stipulated in the previous article and after paying the examination fee of the specified in the (Article Five) of the regulations herein.

2. The concerned department of the competent ministry shall conduct the necessary inspection and prepare a report thereon.

3. In the event of not fulfilling the licensing requirements by the Blood Operations Center in the

first inspection, the center may be granted a grace period not exceeding six months to fulfill the requirement before re-inspection.

4. In the event of failure to fulfill the licensing requirements by the center in the second inspection, another grace period may be granted not exceeding two months. If the results of this inspection failed to fulfill the requirements, the license request shall be rejected.

5. In case of fulfilling the previous conditions and obligations, the remaining documents and prescribed fees shall be completed in accordance with the provisions of the regulations herein.

6. After obtaining the license, the Blood Operations Center must be located in an obvious location in the center.

(Article Four)

The license validity shall be three years, provided that the license renewal request shall be submitted before the expiry of the validity of at least six months.

The same rules of obtaining a license for the first time shall apply to renewal as stated in the regulation herein.

(Article Five)

The registrant shall pay the following fees for registering a Blood Operations Center affiliated to non-governmental bodies:

First- Examination the licensing request charges:

1. Five thousand LE shall be paid for each Blood Storage Bank examination.

2. Ten thousand LE shall be paid for each Blood Collection Bank examination.

3. Ten thousand LE shall be paid for each examination of Blood Plasma Collection Unit for the Purpose of Treatment, taking into account the maximum limit stipulated in Article (Three) of the law herein.

Second- License issuance charges:

1. Thirty thousand LE shall be paid for Blood Storage Bank.

2. Fifty thousand LE shall be paid for Blood Collection Bank.

3. Fifty thousand LE shall be paid for Blood Plasma Collection Unit for the Purpose of Treatment.

Third- License renewal charges:

1. Fifteen thousand LE shall be paid for Blood Storage Bank.

2. Thirty thousand LE shall be paid Blood Collection Bank.

3. Thirty thousand LE shall be paid for Blood Plasma Collection Unit for the Purpose of Treatment

(Article Six)

The Blood Operations Center shall subject to the periodic supervision and inspection by the relevant department in the competent ministry to ensure the achievement of the requirements and controls stipulated by the law, the regulations herein and the executive decisions issued in this regard.

(Article Seven)

The competent ministry shall receive the complaints submitted by the concerned parties who are dealing with the Blood Operations Center regarding violations of the provisions of the law, the regulations herein or the executive decisions issued in this regard. The competent minister shall issue a decision regulating the procedures for submitting and adjudicating complaints and the method of responding to the complainants.

(Article Eight)

The Blood Operations Center shall issue a card for each blood donor based on the questionnaire designated for that purpose. The following conditions must be fulfilled for its issuance:

1. Donor's approval.

2. Completing the donation process.

(Article Nine)

The donor card shall include the following information:

1. The full name,

2. Date of birth,

3. Nationality,

4. National ID card or passport number for non-Egyptians,

5. Type of donation,

6. Date and place of donation and

The Blood Operations Center may add any other data necessary for the card

(Article Ten)

The competent minister shall determine the necessary specifications and requirements for Blood Operations Centers based on the Blood Operations Control Council presentation, provided that the donor's data shall be linked among themselves by the Blood Operations Centers immediately upon completion of the electronic database to create a national registry for donors. The aforementioned procedures shall be implemented under the supervision of the competent ministry.

(Article Eleven)

The standards and requirements regulating Blood Operations Centers are the minimum limit that guide the licensing authorities of Blood Operations Centers that are not subject to the provisions of the law, except for the amounts of money collected by the licensing authorities stipulated in the law where it shall be the maximum limit.

(Article Twelve)

The Blood Operations Control Council shall be held at the competent ministry or at any other location specified by its chairman. The meeting shall be held upon an invitation of the board chairman at least once every three months or when necessary.

The board meeting shall be considered valid in case of attendance of the majority of its members along with the chairman of the board or his representative attendance.

The decision shall be adopted when they are voted for by the majority of the present members. When votes are equal, the opinion favored by the chairman shall be adopted as a decision.

At the first meeting of the Blood Operations Control Council, the competent minister shall issue a decision of forming an internal committee from members of the Council to prepare the internal regulations of the council's work system. Then the said regulations shall be issued by a decision of the competent minister.

(Article Thirteen)

For the purpose of implementing the powers stipulated in Article (Seven) of the law, the Blood Operations Control Council shall undertake the approval of the national standards for blood transfusion to ensure that the method of work and materials used in blood operations centers are unified.

(Chapter Three)

Plasma collection for manufacturing and exportation of its derivatives

(Article Fourteen)

A committee shall be established headed by the Prime Minister and with the membership of:

1. The competent minister.

2. The Minister responsible for higher education.

3. Board Chairman of the Unified Procurement Authority.

4. Egyptian Drug Authority's board chairman.

5. A representative of the Ministry of Defense chosen by the Minister of Defense.

The committee is mandated to prepare the planes for establishing factories and plasma collection centers; determining their locations based on the data presented by the competent minister in coordination with all concerned authorities to ensure achieving self-sufficiency; issuing initial approval for its establishment; setting the price equation for the dispensing of plasma periodically, so that the price of dispensing in the local market is linked to the international prices; issuing the necessary recommendations for achieving the localization of the plasma derivatives industry within the framework of the national project to achieve self-sufficiency in plasma derivatives; determining the mechanisms for providing the necessary financial funds based on data presented by the competent minister to ensure the sustainability of plasma collection operations for the purpose of manufacturing.

The committee shall be held at least once every three months by an invitation of its chairman or whenever necessary.

The committee's chairman may invite to the meetings whomever he deems appropriate to use his experience or opinion on a specific topic, without having a counted vote.

(Article Fifteen)

The decision of issuance and renewal the license of blood plasma collection centers shall be issued by the Egyptian Drug Authority's president, in accordance with the regulatory procedures and technical requirements issued by the Egyptian Drug Authority, guided by the international standards.

The license is granted to any government agencies or private companies in which the state contributes, any of the ministries or any of the public law persons have a controlling share whenever these centers are contracted with an international company specializing in the field of manufacturing plasma derivatives and subjected to its technical supervision.

The license applicant shall be the owner of a licensed factory within the Arab Republic of Egypt in order to license the plasma collection centers owned by other private law persons in accordance with to the law provisions.

(Article Sixteen)

The license request shall be submitted to the Egyptian Drug Authority on the application form designated for that purpose. The submitted request shall be examined within a period not exceeding seven working days and the specified charges shall be paid.

The request shall be signed by the license applicant, his legal representative or his delegated person attached with the following documents:

a) The data of the center director (a human physician), including (his name, title, nationality and place of residence), provided that he must have experience in the field of blood transfusion.

b) An official extract of the following certificates: A certificate of specialization in the various branches of medicine, a training and qualification certificate from the entity requesting the license and a license to practice the profession issued by the competent ministry).

The request shall be accompanied by the national ID card, (4) personal photos, a copy of the membership card of the Egyptian Medical Syndicate and the criminal status record.

(Article seventeen)

The following general requirement shall be available in the plasma collection centers:

1. Its primary activity shall be collecting plasma from donors for the purpose of manufacturing in accordance with the provisions of the law herein. The centers may carry out one of the activities related to plasma collection such as analysis or storage.

2. The technical requirements and standards determined by the Egyptian Drug Authority shall be fully implemented, guided by the standards approved by the international organizations.

3. The instructions and requirements of the civil protection in the facility, including (fire alarms, fire tanks, securing stores, implementing electrical works in accordance with the Egyptian code and providing generator rooms), shall be implemented.

4. Providing a spare electric generator to operate the devices in the event of a power outage.

(Article Eighteen)

The necessary licensing inspection shall be carried out to verify fulfillment of the required technical requirements and standards that shall be applied within thirty working days starting from the day following of submission of the documents which indicate the fulfillment of necessary requirements.

The license issued for the plasma collection center is valid for three years and it shall be renewed via a request submitted at least 6 months before the license expiry.

The same procedures followed in licensing a plasma collection center shall be applied in the case of adding new activities to the plasma collection center.

The plasma collection center shall subject to periodic supervision and inspection by the Egyptian Drug Authority to verify the applying of the technical requirements and standards.

(Article Nineteen)

All plasma collection centers shall be committed to link the data of donors via an electronic system.

(Article Twenty)

The issuance and renewal of the factory's technical operation license whose main purpose is to manufacture blood plasma derivatives shall be issued by the Egyptian Drug Authority in coordination with the Unified Procurement Authority guided by applicable international standards.

(Article Twenty-One)

The same procedures for licensing a plasma collection center shall be followed to license a factory, all in accordance with the international guiding standards and the Egyptian reference guide in this regard and in coordination with the Unified Procurement Authority.

The technical operation license of the factory whose main purpose is to manufacture human blood plasma derivatives shall be renewed every year five Gregorian years after paying the charges specified in accordance with the Article (Twenty-two) of the regulations herein.

A separate store license shall be granted in accordance with the technical controls and requirements followed in this regard the Egyptian Drug Authority is subject, taking into account the technical good storage practices for storing plasma, its derivatives and its supplies.

(Article Twenty-two)

The license applicant of a blood plasma collection center or factory for a non-governmental entity shall pay the following charges:

First- License request examination charges:

1. Twenty thousand LE for the plasma collection center.

2. Forty thousand LE for the factory.

Second- License issuance charges:

1. Seventy-five thousand LE for the plasma collection center.

2. The factory shall pay two hundred thousand.

Third- License renewal charges:

1. The plasma collection center shall pay thirty-five thousand LE.

2. The factory shall pay one hundred thousand LE.

(Article Twenty-Three)

The Egyptian Drug Authority, in coordination with the Unified Procurement Authority, shall issue a decision to control the dispensing of plasma by collection centers, transferring of plasma for manufacturing then recovery and plasma exportation, provided that the decision shall include, in particular:

1. The dispensing, transferring or exporting of the plasma shall be carried out via a specialized Egyptian company which its main purpose is collecting, transferring for manufacturing, exporting, manufacturing and importing plasma or its derivatives for the purposes of the pharmaceutical industry.

2. A statement of the requirements of achieving the localization of the plasma derivatives industry within the framework of the national project for self-sufficiency in plasma derivatives.

(Article Twenty-four)

The Egyptian Drug Authority, in coordination with the Unified Procurement Authority, shall issue a decision on the provisions, rules and procedures of dispensing of blood plasma by the factory subjected to the law provisions by selling or exporting, as well as the decision shall include importing and exporting of the blood plasma derivatives as finished products, provided that the decision shall include, in particular:

1. The dispensing, transferring or exporting of the plasma shall be carried out via a specialized Egyptian company whose main purpose is collecting, transferring for manufacturing, exporting, manufacturing and importing plasma or its derivatives for the purposes of the pharmaceutical industry.

2. A statement of the requirements of achieving the localization of the plasma derivatives industry within the framework of the national project for self-sufficiency in plasma derivatives.

(Article Twenty-five)

The donor shall be given a compensation for the expenses he incurred for the sake of donation, not less than two hundred LE and not exceed three hundred and fifty LE for one donation session. These minimum and maximum limits shall be reconsidered every five years.

(Chapter Four)

General Provisions:

(Article Twenty-six)

In all cases, the donation shall be carried out by a free will that is not tainted by error, fraud or coercion and free of defects of consent and confirmed by a written acknowledgment by the donor. The following conditions shall be fulfilled to accept the donation:

1. The donor shall not be less than 18 years old or over 60 years old.

2. The donor shall have a national number or a passport for non-Egyptians.

3. The donor shall personally sign the acknowledgment of the donation approval.

4. The medically unfit donor shall be excluded without any other reasons for discrimination.

5. All of the necessary tests shall be conducted to prove the donor's safety and ability to donate.

6. The plasma donor shall be medically fit after conducting the medical and laboratory examination in order to become a regular plasma donor.

7. The plasma donor shall comply with the criteria for selecting donors.

8. The plasma donor may donate 104 times as a maximum of a year, twice per week (48 hours as an intervening period between each session).

9. The plasma donor shall be considered a regular donor if he donates at least twice within a period of 6 months.

10. The plasma donation shall be commensurate with the donor's weight, with a maximum of 880 ml for each donation session.

(Article Twenty-seven)

The donor shall be exposed to the following medical examinations:

In the case of blood donation: The blood pressure, pulse, temperature and hemoglobin or hematocrit ratio shall be measured before each donation. In the case of plasma donation, the percentage of total proteins shall be added to the previous tests.

The following serological tests shall be conducted on the blood before using:

1. Hepatitis testing by using HBSAg.

2. Hepatitis C test by using HCV Ab

3. AIDS test 1+2 HIV Ab

4. Syphilis Ab test (each 120 days in the case of plasma donation).

5. DNA examination for a virus HCV -HIV-HBV-B 19 -HAV-Parvo B19 in the case of plasma donation.

In all cases, the competent minister of health may add other tests in accordance with the standards applicable in this regard, provided that this decision shall be published in the Egyptian Gazette.

(Article Twenty-eight)

It shall be prohibited to dispense the blood to patients before conducting the serological tests, ensuring of its negation and recording their tests result in the records of the Blood Operations Center. The tests result for each unit of blood shall be approved by the examining and analyzing physician.

(Article Twenty-nine)

It shall be prohibited to release any units of blood or its components except after conducting the serological tests and ensuring their negation.

The sealed customs release shall not be permissible for the imported or donated plasma for manufacturing purposes and intermediate plasma derivatives unless fulfilling all the documents and requirements determined by the Egyptian Drug Authority and ensuring their freeness of all infectious diseases and viruses that are determined by a decision issued by the competent minister in coordination with the Egyptian Drug Authority. The final release shall not be issued by the Egyptian Drug Authority until fulfilling the requirements of the Authority, testing samples of all batches of the finished products in which plasma was used in their manufacture, issuing an approved and official certificate by the Authority stipulating the batch conformity to the specifications of the product and freeness of the viruses and diseases referred to.

The medical sealed customs release of imported consignments of the finished plasma derivatives, final release and follow-up shall take place by the Egyptian Drug Authority after fulfilling all procedures and rules applied by the Authority regarding the import of biological finished products.

(Chapter Five)

Administrative closure and annulation of the licensing decision

(Article Thirty)

The competent body for issuing the Blood Operations Center license may administratively close it in any of the following cases:

1. If it is managed without a license.

2. If it is managed without a supervision of a human physician at the center.

3. Failure to comply with the decisions regulating the prices of blood and its derivatives.

The closure shall be for a period not exceeding one year, except for the first case, where the closure shall be extended until issuing the license.

(Article Thirty-one)

The competent body for issuing the Blood Operations Center license may annul its license in any of the following cases:

1. Failure to comply with the national standards, according to their latest editions in all work procedures in the Blood Operations Center, as well as failure to fulfill the observations contained in the report issued by the relevant department in the competent ministry.

2. Existence of expired blood units and blood products for more than a day in the dispensing refrigerator.

3. Preserving the blood and its derivatives at temperatures that do not conform to the national standards.

4. Existence of units of blood and its derivatives without a label indicating the negation of the serology tests in the dispensing refrigerator.

5. Donating blood or its derivatives in a Blood Storage Bank.

6. Dispensing blood or its derivatives although the positivity of any of the serological tests of the sample.

7. Dispensing expired blood or its derivatives.

8. Assigning the work in the Blood Operations Center to non-qualified personnel for the center's tasks in accordance with the license issued to it.

9. Existence of an unknown origin unit of blood or its derivatives.

10. Failure to comply with the controls of the number of the donation times for each person can donate according to the requirements of the competent ministry.

(Article Thirty-two)

The competent authority of issuing the licenses for the plasma collection centers or factories has the right to close it administratively in the following cases:

1. In the event of violation of one of the licensing and inspection conditions in accordance with results of the relevant committees. The Egyptian Drug Authority shall have the right to sus-

pend the violating activity. After that, the Authority shall have the right to grant a grace period to correct the defective status. In case of continuous of failure to meet the technical requirements, the activity license shall be cancelled.

2. In case of there are center / factory practicing the activity without obtaining the necessary licenses.

3. In case of managing a plasma collection center without a supervision of a human physician.

4. In case of managing a plasma derivatives manufacturing factory without a factory manager or quality control manager.

5. In case of approval of the competent authority to the request submitted by the applicant to suspend the activity for a specified period.

The closure shall be mandatory in case of failure to remove the violation within six months from the date of issuance the decision of closing and notify him the violation committed and in case of recurrence the violation the closing will be mandatory.

The period of closure shall not be less than three months and not exceed one year, except for the second case, in which the center / factory shall be closed until issuance the license.

(Article Thirty-three)

The competent authority of issuing the licenses for the plasma collection centers has the right to cancel its license in any of the following cases:

1. In the case of the technical requirements required to be fulfilled for licensing or inspection were violated and not addressed for a period of six months from the date of notifying the center or factory of the violation reasons.

2. In case of managing a plasma collection center without a supervision of a human physician.

3. If the plasma collection center does not carry out any activity for a full Gregorian year.

The competent authority of issuing the licenses for the factory has the right also to cancel its license in any of the following cases:

1. In the case of the technical requirements required to be fulfilled for licensing or inspection were violated and not corrected for a period of six months from the date of the violation.

2. In case of managing the factory without a plant manager or a quality control manager.

3. If the factory does not carry out any activity for a full Gregorian year.

(Article Thirty-four)

The closure shall be by a reasoned decision by the competent authority for issuing the license, as the case may be. The concerned parties shall be notified of the decision immediately upon its issuance.

(Chapter Six)

Grievances:

(Article Thirty-fife)

The concerned parties may file a grievance against the administrative decisions issued by the competent ministry regarding Blood Operations Centers, in accordance with the provisions of the law and the decisions issued in implementation thereof. The grievance shall be fulfilling all the documents and shall be examined and adjudicated within sixty days of its receipt by a committee formed for this purpose by a decision of the competent minister.

Failure to respond to the grievance within the prescribed period shall be considered a rejection of the grievance.

(Article Thirty-six)

The concerned parties may file a grievance against the administrative decisions issued by the Egyptian Drug Authority regarding plasma collection centers and the factories. The grievance and its adjudicated shall be submitted in accordance with the provisions and procedures set forth in the executive regulations of the law establishing the Egyptian Authority for Unified Procurement and Medical Supplies and Administration of Medical Technology and the Egyptian Drug Authority issued by Law No. (151) of 2019.