

CHAPTER 483

HUMAN BLOOD AND TRANSPLANTS ACT

To regulate the collection and testing of human blood and blood components and to establish standards of quality and safety for human tissues and cells intended for human transplants.

15th September, 2006

ACT IV of 2006, as amended by [Legal Notice 427 of 2007](#).

1. The short title of this Act is the Human Blood and Transplants Act. Short title.

PART I

PRELIMINARY

2. In this Act, unless the context otherwise requires - Interpretation.

"allogenic use" means cells or tissues removed from one person and applied to another;

"autologous transfusion" means transfusion in which the donor and the recipient are the same person and in which pre-deposited blood and blood components are used;

"autologous use" means cells or tissues removed from and applied in the same person;

"blood" means whole blood collected from a donor and processed either for transfusion or for further manufacturing;

"blood component" means a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;

"blood component release" means a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

"blood establishment" means any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion, but does not include a hospital blood bank;

"blood product" means any therapeutic product derived from human blood or plasma;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue;

"the Commission" means the European Commission;

"deferral" means suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary;

"[Directive 2004/23/EC](#)" means the Commission Directive 2004/23/EC of the European Parliament and of the Council of 31 March,

2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

"[Directive 2004/33/EC](#)" means the Commission Directive 2004/33/EC of 22 March, 2004 implementing [Directive 2002/98/EC](#) of the European Parliament and of the Council as regards certain technical requirements for blood and blood components;

"distribution" means in the case of blood and blood components, the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusions. In the case of human tissues and cells "distribution" means transportation and delivery of tissues or cells intended for human application;

"donor" means every human source, whether living or deceased, of human cells or tissues;

"donation" means donating human tissues or cells intended for human applications;

"establishment" includes a blood establishment and a tissues and cells establishment;

"haemovigilance" means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

"hospital blood bank" means a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

"human application" means the use of tissues or cells on or in a human recipient and extracorporal applications;

"inspection" means formal and objective control to identify problems in accordance with standards adopted to assess compliance with these regulations;

"the Licensing Authority" means the Superintendent of Public Health as established in article 3(1);

"the Medicines Authority" means the Licensing Authority established under the [Medicines Act](#);

"organ" means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

"processing" means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;

"procurement" means a process by which tissues or cells are made available;

"preservation" means the use of chemical agents, alterations in

environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;

"quarantine" means the status of retrieved tissues or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;

"serious adverse event" means in the case of blood and blood components, any untoward occurrence associated with the collection, testing, processing, storage, and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity; and in the case of tissues and cells means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" in the case of blood and blood components means an unintended response in donor or in patient associated with the collection or transfusion of blood and blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity; in the case of tissues and cells it means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

"storage" means maintaining the product under appropriate controlled conditions until distribution;

"tissue" means all constituent parts of the human body formed by cells;

"tissues and cells establishment" means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells;

"qualified health professional" includes a doctor, nurse and any health professional regulated by the [Health Care Professions Act](#).

Cap. 464.

PART II

THE LICENSING AUTHORITY

3. (1) The Superintendent of Public Health shall be the Licensing Authority for the purposes of this Act.

Functions of the
Licensing
Authority.

(2) The Licensing Authority, hereinafter referred to as the Licensing Authority, shall have the following functions:

- (a) to verify that the establishments are in compliance with the requirements set out under this Act and any regulations made thereunder;

- (b) to indicate to the establishment which activities it may undertake;
- (c) to establish conditions applicable to establishments;
- (d) to issue, renew, amend, vary, suspend or revoke any licence that may be required by or under this Act;
- (e) to carry out inspections of establishments and organize control measures in such establishments regularly and in any case not less than once every two years;
- (f) to conduct such additional inspections of establishments as it considers necessary for the purpose of ensuring compliance with the requirements of this Act and any regulations made thereunder;
- (g) to inspect hospital blood banks to ensure that such banks and persons responsible for the management of such banks comply with the requirements of this Act and any regulations made thereunder;
- (h) to organize, in the event of any serious adverse event or reaction or suspicion thereof, inspections and other control measures;
- (i) to establish guidelines concerning the conditions of the inspections and control measures, and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance;
- (j) to establish and maintain a publicly accessible register of tissue establishments specifying the activities for which they have been licensed;
- (k) to do all such things as may be necessary for the purpose of ensuring compliance with any of the provisions of this Act or regulations made thereunder.

(3) The Licensing Authority may by rules delegate any of the functions referred to in subarticle (2) to the Medicines Authority, or any other authority or institution it deems competent.

(4) The Licensing Authority shall levy such fees as may be prescribed for the purpose of this Act.

PART III

BLOOD ESTABLISHMENTS AND HOSPITAL BLOOD BANKS

Inspections and
control measures.

4. The inspections and control measures of blood establishments and hospital blood banks shall be carried out by any person duly authorized in writing by the Licensing Authority and shall, on production of this authorization, have a right to:

- (a) inspect at any reasonable hour:
 - (i) any premises owned or managed by a blood establishment or person responsible for management of a hospital blood bank, or at which the blood establishment or person responsible for management of a hospital blood

bank carries out any of the activities referred to in this Part of this Act;

- (ii) any premises of any person who carries out any of the activities referred to in this Part of this Act on behalf of, and pursuant to a contractual arrangement with, a blood establishment or a person responsible for management of a hospital blood bank; and
 - (iii) where any facilities for donor evaluation and testing are in the premises of any person other than a blood establishment or hospital blood bank, those facilities in that person's premises;
- (b) to require the production of, and inspect any article or substance at the premises;
 - (c) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record, in whatever form held at the premises, or any computer data or records which are accessible thereat;
 - (d) to take possession of any samples for examination and analysis and any other article, substance, book, document, data, record in whatever form held at the premises, or any computer data or records which are accessible thereat;
 - (e) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;
 - (f) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities;
 - (g) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him;
 - (h) carry out any activity he may deem appropriate for the proper execution of his duties and responsibilities as provided by this Act and any regulations made thereunder.

5. (1) It shall not be lawful for any person to carry out any activity listed in subarticle (2) other than in accordance with a licence issued under article 3.

Licensing of blood establishments.

(2) he activities referred to in sub-article (1) are:

- (a) the collection of human blood components, whatever their intended purpose; and
- (b) the testing of human blood components, whatever their intended purpose; and
- (c) their preparation, storage and distribution when intended for transfusion, unless any such activity is undertaken in a blood establishment licensed for that purpose by the Licensing Authority.

- (3) A licence shall not be required for -
- (a) the storage and distribution of, and the performance of compatibility tests on, blood and blood components exclusively for use within hospital facilities, including transfusion activities where such activities are performed by a hospital blood bank; or
 - (b) any person carrying out any of the activities referred to in subarticle (2) where that person carries out that activity on behalf of, and pursuant to, a contractual arrangement with -
 - (i) a blood establishment which is licensed under this Part to carry out the activity in question; or
 - (ii) a person responsible for the management of a hospital blood bank.
- (4) The application for the grant of a licence shall be made to the Licensing Authority and shall be accompanied by the prescribed fee.
- (5) The application shall contain the information as may be prescribed and shall be submitted in the form and in the manner as may by rules be laid down by the Licensing Authority.
- (6) Where an application is received by the Licensing Authority, it may -
- (a) grant or refuse any application;
 - (b) grant such licence in respect of particular sites or activities only;
 - (c) grant such licence subject to conditions;
 - (d) refuse to process the application if such application has not been submitted in accordance with this Act and regulations made thereunder;
 - (e) request the applicant to furnish it with additional information as it may deem necessary.
- (7) When the Licensing Authority grants a licence following an application, it shall give notice in writing to the blood establishment specifying -
- (a) the activities which the blood establishment may undertake under this Act and regulations made thereunder at each site in respect of which licence is granted; and
 - (b) the conditions which apply to the undertaking of those activities.
- (8) The Licensing Authority may at any time remove or vary any of the licence conditions, or may impose additional conditions.
- (9) When the Licensing Authority removes or varies any condition or imposes any additional condition the Licensing Authority shall inform in writing the blood establishment in question giving reasons for its decision.
- (10) A blood establishment may not make any substantial

change in the activities which it undertakes without the prior written approval of the Licensing Authority.

(11) Any application for approval to make a substantial change in its activities shall be made in writing to the Licensing Authority, and shall be accompanied by the prescribed fee.

(12) For the purpose of this article, a substantial change in a blood establishment's activities is any change -

- (a) to the sites from which the blood establishment operates or to the activities to be carried out at each site;
- (b) which would result in breach of this Act or regulations made thereunder or of any condition specified by the Licensing Authority; or
- (c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of those activities which the blood establishment has been licensed to undertake.

6. (1) The Licensing Authority may suspend or revoke the licence of a blood establishment on one or more of the following grounds:

Revocation or suspension of licence.

- (a) that the blood establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder;
- (b) that the collection, testing, processing, storage or distribution of blood or blood components by the blood establishment cannot be carried out safely;
- (c) that any blood or blood components cannot be supplied to hospital blood banks in such a state that they could be safely administered for transfusion; or
- (d) that the information given by the blood establishment was false or incomplete in any material respect.

(2) Prior to suspending or revoking the licence of a blood establishment, the Licensing Authority shall serve a notice on the blood establishment stating that it intends to suspend or revoke its licence with effect from the date specified in the notice, giving reasons for such decision:

Provided that a suspension or revocation shall take effect immediately when the Licensing Authority considers that it is necessary in the interests of safety.

(3) In those cases where -

- (a) the blood establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder; or
- (b) the information given by the blood establishment was false or incomplete in any material respect,

and the Licensing Authority considers that the failure in question is

not sufficiently serious to warrant suspension or revocation of the licence of the blood establishment in the first instance, the Licensing Authority may serve a notice on the responsible person of the blood establishment:

- (i) identifying the requirements of which the blood establishment is in breach or, in the case of false and incomplete information, the further information which is required;
- (ii) identifying the action which the blood establishment is required to take; and
- (iii) giving the timescale within which the blood establishment shall take the action identified in the preceding subparagraph.

(4) If the blood establishment fails to comply with the requirements set out in the notice within the specified timescale, the Licensing Authority may, by a notice served on the blood establishment, suspend or revoke the licence of the blood establishment.

(5) Any suspension shall be for such period as the Licensing Authority shall consider necessary having regard to the reasons for the suspension.

(6) The suspension or revocation of an licence may be total, or limited to a particular activity or to one or more activities carried out at a particular site or sites, or to a particular blood component.

Notice served on
hospital blood
banks.

7. (1) If the Licensing Authority is of the opinion that -
- (a) the person responsible for management of a hospital blood bank has failed, in any material respect, to comply with the requirements of these articles; or
 - (b) the testing, storage or distribution of blood or blood components by the hospital blood bank is such that any blood or blood components cannot be safely administered for transfusion; or
 - (c) the information given by the person responsible for management of a hospital blood bank was false or incomplete in any material respect,

the Licensing Authority may serve a notice on the person responsible for management of the hospital bank requiring that the hospital ceases to conduct any of this Activities specified in the notice, or refrains from administering to patients any blood or blood components specified in the notice, until the conditions set out in the notice are complied with.

(2) Any notice served by the Licensing Authority pursuant to subarticle (1) shall specify the date from which the prohibition specified in the notice shall take effect, which shall be not less than seven days from the date on which the notice is served:

Provided that where the Licensing Authority considers that it is necessary in the interests of safety, it may specify in the notice that the prohibition takes immediate effect.

- (3) The notice shall be withdrawn if:
- (a) the person responsible for management of the hospital blood bank is no longer in breach of the requirements of these articles;
 - (b) the hospital blood bank is able to show that the activity or product referred to in the notice given pursuant to subarticle (1)(b) may be safely carried out or, as the case may be, administered; or
 - (c) all necessary information has been supplied to the Licensing Authority.
- 8.** (1) Every licence granted under this Act shall, unless previously revoked or renewed, expire at the end of its period of validity. Validity of licence.
- (2) Every licence shall, unless previously revoked, be renewable upon application by the holder made at least three months before the expiry of the period of validity.
- 9.** No person shall import into Malta any blood or blood components, including blood or blood components intended for use as a starting material or raw material in the manufacture of medicinal products, from a country or territory outside the European Community which does not meet standards of quality and safety equivalent to those laid down in Annex V of [Directive 2004/33/EC](#) and any amendments thereto. Importation.
- 10.** (1) Where the Licensing Authority is aware of a specific epidemiological situation, such as an outbreak of a disease, which may affect the safety of blood donations, and as a result of which it considers that specific deferral criteria for the collection of blood donations should be adopted, it shall notify: Specific epidemiological situations.
- (a) the blood establishments that those criteria must be adopted; and
 - (b) the Commission of the epidemiological situation and the additional deferral criteria which blood establishments are required to adopt in relation to it pursuant to paragraph (a).
- (2) A blood establishment shall adopt and comply with any criteria for additional tests notified to them by the Licensing Authority pursuant to subarticle (1).

PART IV

TISSUES AND CELLS ESTABLISHMENTS

- 11.** The inspections and control measures of tissues and cells establishments shall be carried out by any person duly authorized in writing by the Licensing Authority and such person shall, on production of his authorization, have a right to: Inspection and control measures.
- (a) inspect at any reasonable hour:
 - (i) any premises owned or managed by a tissues and cells establishment, or at which the tissues and

- cells establishment carries out any of its activities in relation to the procurement of human tissues and cells;
- (ii) any premises of any person who carries out any of the activities referred to above on behalf of, and pursuant to a contractual arrangement with, a tissues and cells establishment; and
 - (iii) where any facilities for donor evaluation and testing are in the premises of any person other than a tissues and cells establishment, those facilities in that person's premises;
- (b) to require the production of and inspect any article or substance at the premises;
 - (c) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record, in whatever form it is held at the premises, or any computer data or records accessible thereat;
 - (d) to take possession of any samples for examination and analysis and any other article, substance, book, document, data, record, in whatever form they are held at the premises, or any computer data or records accessible thereat;
 - (e) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;
 - (f) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities;
 - (g) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him;
 - (h) to evaluate and verify the procedures and the activities carried out in tissues and cells establishments and the facilities of third parties that are relevant to the requirements of this Act and regulations made thereunder;
 - (i) carry out any activity he may deem appropriate for the proper execution of his duties and responsibilities as provided by this Act and regulations made thereunder.

Supervision and
licensing.

12. (1) It shall not be lawful for any person to carry out any activity in connection with testing, processing, preservation, storage or distribution of human tissue and cells intended for human applications otherwise than in accordance with a licence issued under article 3.

(2) A licence shall not be required for -

- (a) the storage and distribution of, and the performance of compatibility tests on, tissues and cells exclusively for use within hospital facilities; or

- (b) any person carrying out any of these activities referred to in subarticle (1), where that person carries out that activity on behalf of, and pursuant to a contractual arrangement with a tissues and cells establishment which is licensed under this Part to carry out the activity in question;
 - (c) the direct distribution of specified tissues and cells for immediate transplantation to the recipient as long as the supplier is licensed for such activity.
- (3) The application for the grant of a licence shall be made to the Licensing Authority and shall be accompanied by the prescribed fee.
- (4) The application shall contain the information as may be prescribed and shall be submitted in the form and in the manner as may by rules be laid down by the Licensing Authority.
- (5) Where an application is received by the Licensing Authority, it may -
 - (a) grant or refuse any application;
 - (b) grant such licence in respect of particular sites or activities only;
 - (c) grant such licence subject to conditions;
 - (d) refuse to process the application if such application has not been filed in accordance with this Act and regulations made thereunder;
 - (e) request the applicant to furnish it with additional information as it may deem necessary.
- (6) When the Licensing Authority grants an application for licence, it shall give notice in writing to the tissues and cells establishment specifying -
 - (a) the activities which the establishment may undertake under this Act and regulations made thereunder at each site in respect of which a licence is granted;
 - (b) the conditions which apply to the undertaking of those activities; and
 - (c) the tissues and cells preparation processes which the establishment may carry out.
- (7) The Licensing Authority may at any time remove or vary any of the licence conditions, or may impose additional conditions.
- (8) When the Licensing Authority removes or varies any condition or imposes any additional condition, it shall inform in writing the establishment in question giving reasons for its decision.
- (9) A tissues and cells establishment may not make any substantial change in the activities which it undertakes without the prior written approval of the Licensing Authority.
- (10) Any application for approval to make a substantial change in the activities of the tissues and cells establishment shall be made

in writing to the Licensing Authority, and shall be accompanied by the prescribed fee.

(11) For the purposes of this article, a substantial change in a tissues and cells establishment's activities is any change -

- (a) to the sites from which the establishment operates or to the activities to be carried out at each site;
- (b) which would result in breach of this Act or regulations made thereunder or of any condition specified by the Licensing Authority; or
- (c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the activities which the establishment has been licensed to undertake.

(12) The Licensing Authority shall suspend or revoke the licence of a tissues and cells establishment or of a tissue or cell preparation process if inspections or control measures demonstrate that such an establishment or process does not comply with the requirements of this Act and regulations made thereunder.

Revocation or suspension of licence.

13.(1)(a) The Licensing Authority may suspend or revoke the licence of a tissues and cells establishment on one or more of the following grounds:

- (i) that the establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder;
 - (ii) that the information given by the blood establishment was false or incomplete in any material respect.
- (b) In addition the Licensing Authority shall suspend or revoke the licence of a tissues and cells establishment or of a tissues or cells preparation process if inspections or control measures demonstrate that such an establishment or process does not comply with the requirements of this Act and regulations made thereunder.

(2) Prior to suspending or revoking the licence of a blood establishment, the Licensing Authority shall serve a notice on the blood establishment stating that it intends to suspend or revoke its licence with effect from the date specified in the notice, giving reasons for such decision:

Provided that such suspension or revocation shall take effect immediately when the Licensing Authority considers that it is necessary in the interests of safety.

(3) In those cases where -

- (a) the establishment has failed, in any material respect, to comply with the requirements of this Act or regulations made thereunder; or
- (b) the information given by the establishment was false or incomplete in any material respect, and the

Licensing Authority considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the licence of the establishment in the first instance,

the Licensing Authority may serve a notice on the responsible person of the establishment:

- (i) identifying the requirements of which the establishment is in breach or, in the case of false and incomplete information, the further information which is required;
- (ii) identifying the action which the establishment is required to take; and
- (iii) giving the timescale within which the blood establishment shall take the action identified in subparagraph (ii).

(4) If the establishment fails to comply with the requirements set out in the notice within the specified timescale, the Licensing Authority may, by a notice served on the establishment, suspend or revoke the licence of the establishment.

(5) Any suspension shall be for such period as the Licensing Authority shall consider necessary having regard to the reasons for the suspension.

(6) The suspension or revocation of an licence may be total, or limited to a particular activity or to one or more activities carried out at a particular site or sites, or to a particular tissue and cell.

14. (1) Every licence granted under this Act shall, unless previously revoked or renewed, expire at the end of its period of validity.

Validity of licence.

(2) Every licence may, unless previously revoked, be renewed upon application by the holder made at least three months before the expiry of the period of validity.

15. (1) No person shall import tissues and cells from third countries unless:

Import or export of human tissues and cells.

- (a) such an activity is undertaken by a licensed tissues and cells establishment;
- (b) the imported tissues and cells can be traced from the donor to the recipient and vice versa in accordance with the procedures established by regulations under this Act;
- (c) the tissues and cells establishments that receive such imports from third countries ensures that they meet standards of quality and safety equivalent to the ones laid down in [Directive 2004/23/EC](#).

(2) No person shall export tissues and cells to third countries unless:

- (a) such activity is undertaken by a licensed tissues and cells establishment;

(b) such exports to third countries complies with the requirements of [Directive 2004/23/EC](#).

(3) The Licensing Authority may, after ensuring that the that imports and exports of tissues and cells referred to in subarticle (2) meet quality and safety standards equivalent to those laid down in [Directive 2004/23/EC](#), directly authorise:

- (a) the import or export of tissues and cells referred to in article 12(2)(c);
- (b) the import or export of certain tissues and cells in case of emergency.

PART V

MISCELLANEOUS

Power of the Minister to make regulations.

16. The Minister may, after consultation with the Licensing Authority, by regulations provide for -

- (a) the requirements to be satisfied by blood and tissues and cells establishments;
- (b) standards of good practice in manufacture;
- (c) the requirements to be satisfied by hospital blood banks;
- (d) the requirements to establish an effective system of haemovigilance;
- (e) prescription of the fee to be paid for the issue of a licence;
- (f) any other matter to better put into effect the provisions of this Act.

Offences and penalties.
Amended by:
L.N. 427 of 2007.

17. Any person who fails to comply with any of the provisions of this Act or any regulations or rules made thereunder, shall be guilty of an offence and shall, on conviction, be liable a fine not exceeding eleven thousand and six hundred and forty-six euro and eighty-seven cents (11,646.87).

Special procedure.
Amended by:
L.N. 427 of 2007.

18. (1) Notwithstanding any other law providing for the trial of offences, where the Authority believes that a person has committed an offence against this Act or any regulations made thereunder, the Licensing Authority shall give notice in writing to such person describing the offence of which the person is accused, indicating the steps to be taken to remedy the offence and the penalty he is required to pay in respect of that offence.

(2) The Minister shall prescribe the penalties that may be demanded by the Licensing Authority in relation to any specified offence:

Provided that such penalty shall not exceed the amount of eleven thousand and six hundred and forty-six euro and eighty-seven cents (11,646.87).

(3) Where a notice under this article has been given, the person named in the notice may, within twenty-one days of the service of the notice, accept responsibility for the offence specified in the notice and within the same period pay the penalty indicated in the

notice, and comply with the relative provision of this Act, or of the regulations or rules made thereunder and no further proceedings may be taken under this Act in respect of such offence.

(4) Where the person to whom notice is given under subarticle (1) has not paid the penalty within the twenty-one day period referred to in subarticle (3) and has not, within the time specified, complied with the requirements of this Act, criminal proceedings may be taken against him in accordance with the provisions of the [Criminal Code](#), of this Act and of any other law applicable to the offence. Cap. 9.
