

SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 4551 of 08 March, 2019

LEGAL NOTICE NO.045 OF 2019.

EUROPEAN UNION (WITHDRAWAL) ACT 2018

PUBLIC HEALTH (BLOOD SAFETY AND QUALITY) (AMENDMENT) (EU EXIT) REGULATIONS 2019

In exercise of the powers conferred on it by section 11 of the European Union (Withdrawal) Act 2019, the Minister has made the following Regulations—

Title.

1. These Regulations may be cited as the Public Health (Blood Safety and Quality) (Amendment) (EU Exit) Regulations 2019.

Commencement.

2. These Regulations come into operation on exit day.

Amendment to Public Health (Blood Safety and Quality) Act 2007.

3.(1) The Public Health (Blood Safety and Quality) Act 2007 is amended in accordance with this regulation.

(2) In section 2—

- (a) delete the definition of “Commission” in its entirety;
- (b) in the definition of “the principle Directive”, after “components” insert “, as amended from time to time”;
- (c) in the definition of “implementing Directives”, after —
 - (i) “components,” and “events,” insert “as amended from time to time,”; and
 - (ii) “establishments” insert “, as amended from time to time”;
- (d) in the definition of “medical device”, after “concerning medical devices” insert “, as amended from time to time”;
- (e) in the definition of “medicinal product”, after “human use” insert “, as amended from time to time”; and

- (f) in the definition of “third country”, for “outside the European Community” substitute “other than Gibraltar”.
- (3) In section 7, subsection (2), substitute the following for paragraph (b)–
- “(b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under this Act for at least 2 years, in an establishment (or more than one establishment) authorised–
- (i) under section 5; or
- (ii) in a third country where the safety and quality standards for establishments authorised in that country or territory are equivalent to those for establishments authorised in Gibraltar under section 5,
- to undertake activities related to the collection of testing (or both) of blood and blood components, or to their preparation, storage and distribution.”.
- (4) In section 8–
- (a) in subsection (1), delete “Community”; and
- (b) in subsection (3), for “into the European Community” substitute “from a third country”.
- (5) In section 9–
- (a) in subsection (1), for “outside the European Community” substitute “a third country”; and
- (b) in subsection (2), for “into the European Community” substitute “from a third country”.
- (6) In sections 12 and 15, delete “Community”.
- (7) In section 15A, subsection (2), paragraph (a), after “products from human use” insert “, as amended from time to time”.
- (8) In section 19–
- (a) delete “into Gibraltar” on every occasion that it appears, including the section heading; and
- (b) in paragraph (a), delete “Community”.
- (9) Delete section 24.
- (10) In section 26, substitute the following for subsection (1)–

“(1) Where the competent 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 he considers that specific deferral criteria for the collection of blood donations should be adopted, he shall notify blood establishments that those criteria must be adopted.”.

(11) In section 27–

(a) in paragraph (b)–

(i) delete “or any European Union Directive or Regulations”; and

(ii) after “of this Act;” delete “or”;

(b) in paragraph (c), for “Act.” substitute “Act;” and

(c) after paragraph (c), insert–

“(d) in order to amend a schedule to this Act.”.

(12) In Schedule 7–

(a) after “Where relevant, materials, reagents and equipment” insert “shall meet the requirements of Council Directive 93/42/EEC for medical devices, as amended from time to time and Directive 98/79/EC of the European Parliament and of the Council for in vitro diagnostic medical devices, as amended from time to time, or comply with equivalent standards in the case of collection in third countries”;

(b) after “2003/94/EC” insert “ as amended from time to time.”; and

(c) for “competent authorities are” substitute “competent authority is”.

Dated 8th March, 2019.

N.F COSTA,
Minister with responsibility for Health.

EXPLANATORY MEMORANDUM

These Regulations are made in exercise of the powers in section 11 of the European Union (Withdrawal) Act 2019 in order to deal with deficiencies arising from the withdrawal of the United Kingdom and Gibraltar from the European Union.

They amend the Public Health (Blood Safety and Quality) Act 2007 in order to make necessary amendments to enable the Act to continue to operate after withdrawal of the United Kingdom and Gibraltar from the European Union.