

**SECOND SUPPLEMENT TO THE GIBRALTAR
GAZETTE**

No. 4,431 of 25th January, 2018

LEGAL NOTICE NO.22 OF 2018.

INTERPRETATION AND GENERAL CLAUSES ACT

**PUBLIC HEALTH (BLOOD SAFETY AND QUALITY) ACT 2007
(AMENDMENT) REGULATIONS 2018**

In exercise of the powers conferred upon it by section 23(g)(ii) of the Interpretation and General Clauses Act, and in order to transpose into the law of Gibraltar, Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments, the Government has made the following Regulations-

Title.

1. These Regulations may be cited as the Public Health (Blood Safety and Quality) Act 2007 (Amendment) Regulations 2018.

Commencement.

2. These Regulations come into operation on 15 February 2018.

Amendment of Act.

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

(2) After section 15, insert-

“Good practice guidelines.”

15A.(1) The competent authority shall ensure that good practice guidelines for the implementation of the standards and specifications in Schedule 7 are made available to blood establishments and the person responsible for the management of a hospital blood bank.

(2) Good practice guidelines under subsection (1) must fully take into account-

- (a) where relevant for blood establishments, the detailed principles and guidelines of good manufacturing practice, as referred to in the first subparagraph of Article 47 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2007 on the Community code relating to medicinal products for human use; and
 - (b) the Good Practice Guidelines jointly developed by the European Commission and the European Directorate for the Quality of medicines and Healthcare of the Council of Europe and published by the Council of Europe.
- (3) All blood establishments and the person responsible for the management of a hospital blood bank must use the good practice guidelines made available under subsection (1) in the quality system established under section 12(1)(b) or in place under section 15.”

(3) In section 25(1), after “section 15,”, insert “ section 15A(3),”.

Dated 25th January,2018.

N F COSTA,
Minister with responsibility for Health
For the Government.

EXPLANATORY MEMORANDUM

These Regulations transpose into the law of Gibraltar Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments.