
STATUTORY INSTRUMENTS

1992 No.460

**PUBLIC HEALTH, ENGLAND AND WALES
PUBLIC HEALTH, SCOTLAND**

The HIV Testing Kits and Services Regulations 1992

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| <i>Made</i> | - - - - | <i>3rd March 1992</i> |
| <i>Laid before Parliament</i> | | <i>9th March 1992</i> |
| <i>Coming into force</i> | - - | <i>1st April 1992</i> |

In exercise of the powers conferred by section 23(1) and (3) of the Health and Medicines Act 1988⁽¹⁾ and of all other powers enabling me in that behalf, I hereby make the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the HIV Testing Kits and Services Regulations 1992 and shall come into force on 1st April 1992.

(2) In these Regulations unless the context otherwise requires—

- (a) any reference to sale or supply to a member of the public is a reference to sale or supply to a person otherwise than in the course of a business carried on by that person; and
- (b) “business” includes a professional practice and any activity carried on by a body of persons, whether corporate or unincorporate, and the provision of services under the National Health Service Act 1977⁽²⁾, or the National Health Service (Scotland) Act 1978⁽³⁾ or the Health and Personal Social Services Order (Northern Ireland) Order 1972⁽⁴⁾.

Sale or supply of HIV testing kits

2.—(1) Subject to paragraph (2) of this regulation, a person who sells or supplies an HIV testing kit⁽⁵⁾, or any component part of such a kit, to a member of the public shall be guilty of an offence.

(1) 1988 c. 49.

(2) 1977 c. 49.

(3) 1978 c. 29.

(4) S.I.1972/1265 (N.I. 14).

(5) Section 23(6) provides that “HIV” means Human Immunodeficiency Virus of any type; and that “HIV testing kit” means a diagnostic kit the purpose of which is to detect the presence of HIV or HIV antibodies.

(2) A person shall not be guilty of an offence under paragraph (1) above if he proves that, after having exercised all due diligence, he had a reasonable belief that the person to whom he was selling or supplying the kit or component was acting in the course of a business carried on by that person.

Conditions for the sale or supply of kits

3.—(1) A person who sells or supplies to another an HIV testing kit which does not comply with the condition set out in paragraph (2) of this regulation shall be guilty of an offence.

(2) The condition referred to in paragraph (1) of this regulation is that the kit is, at the time of sale or supply, accompanied by a notice which—

- (a) indicates that the kit must not be sold or supplied to a member of the public; and which
- (b) includes a warning that the result of a test which purports to have detected the presence of HIV or HIV antibodies (sometimes described as a “positive” result) should not be relied on unless confirmed by at least one other test result; and which
- (c) in the case of a kit for detecting the presence of HIV antibodies, includes a warning that the result of a test which has failed to detect their presence (sometimes described as a “negative” result) may not have detected recently acquired HIV, for which antibodies have not yet developed.

HIV testing services

4.—(1) Subject to paragraph (2) of this regulation, a person who provides another with HIV testing services⁽⁶⁾ shall be guilty of an offence, unless—

- (a) he is a registered medical practitioner; or
- (b) he provides the services in accordance with the directions of a registered medical practitioner; or
- (c) he provides the services as technical services, such as testing a sample of blood,—
 - (i) in accordance with a request made by a registered medical practitioner, or
 - (ii) for the purposes of detecting the presence of HIV or HIV antibodies in blood given for the purpose of being used for transfusions of blood (whether whole blood, plasma or other blood products).

(2) A person shall not be guilty of an offence under paragraph (1) above if he proves that, after having exercised all due diligence, he had a reasonable belief that he was providing the services in the circumstances specified in sub-paragraph (b) or (c) of that paragraph.

Advertising HIV testing kits and services

5.—(1) Subject to paragraphs (3) and (4) of this regulation, a person who advertises HIV testing kits, or any component parts of such kits, for sale or supply to members of the public shall be guilty of an offence.

(2) Subject to paragraphs (3), (4) and (5) of this regulation, a person who advertises the provision of HIV testing services without stating, in the advertisement, that the services will be provided only by or, as the case may be, in accordance with the directions of a registered medical practitioner shall be guilty of an offence.

(3) A person whose business it is to publish or arrange for the publication of advertisements shall not be guilty of an offence under this regulation if he proves that he received the advertisement in the ordinary course of his business, that the content of the advertisement was not (wholly or in part)

⁽⁶⁾ Section 23(6) provides that “HIV testing services” means diagnostic services the purpose of which is to detect the presence of HIV or HIV antibodies in identifiable individuals.

devised or selected by him or by any person under his direction or control and that he did not know and had no reason for believing that the publication of the advertisement would constitute an offence.

(4) In any proceedings for an offence under this regulation it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of such an offence by himself or any person under his control.

(5) Paragraph (2) of this regulation (offence of advertising HIV testing services) shall not apply to the advertising of technical services the provision of which would meet the requirements of regulation 4(1)(c) of these Regulations.

3rd March 1992

William Waldegrave
One of Her Majesty's Principal Secretaries of
State

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make it an offence, subject to various exceptions,
to sell or supply an HIV testing kit or component to a member of the public (regulation 2)
to sell or supply an HIV testing kit without an accompanying warning notice (regulation 3)
to provide HIV testing services which are not directed by a registered medical practitioner
(regulation 4).
In addition, regulation 5 places restrictions on advertisements for such kits, components and services.