

*Changes to legislation: Medicines Act 1968, Cross Heading: Analysis or other examination of sample is up to date with all changes known to be in force on or before 20 April 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

## SCHEDULES

### SCHEDULE 3

#### SAMPLING

##### Modifications etc. (not altering text)

- C1** Sch. 3 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3), 3**  
Sch. 3 applied (3.10.1994) by S.I. 1994/2328, **reg. 11(c)**  
Sch. 3 applied (with modifications) (1.1.1995) by S.I. 1994/3144, **reg.10, Sch. 4**  
Sch. 3 applied (31.3.1997) by S.I. 1997/322, **reg. 34, Sch.5**  
Sch. 3 applied (1.2.2000) by S.I. 2000/7, **reg. 5**
- C1** Sch. 3 applied (with modifications) (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), **regs. 1, 47, Schs. 9**
- C1** Sch. 3 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), **regs. 1(a), 11, Schs. 4** (with Sch. 6)
- C1** Sch. 3 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), **regs. 1(1), 32**

##### *Analysis or other examination of sample*

- 15 If the sampling officer decides to submit the sample for analysis or other appropriate examination, he shall—
- (a) submit it for analysis to the public analyst for the area in which the sample was obtained, or, if for the time being there is no public analyst for that area, then to the public analyst for some other area, or
  - (b) submit it for other appropriate examination to the person having the management or control of any laboratory available for the purpose in accordance with any arrangements made in that behalf by the relevant enforcement authority.
- 16 Where the relevant enforcement authority is a Minister or the Pharmaceutical Society, and the sampling officer decides to have the sample analysed, he may (instead of submitting it to a public analyst) submit it for analysis to the person having the management or control of any laboratory available for the purpose in accordance with any arrangements made in that behalf by the relevant enforcement authority.
- 17 Any such arrangements as are mentioned in paragraph 15(b) or paragraph 16 of this Schedule,—
- <sup>F1</sup>(a) .....
  - (b) if <sup>F2</sup>... they are made by an enforcement authority in England and Wales other than [<sup>F3</sup>the Secretary of State], shall be arrangements approved by [<sup>F3</sup>the Secretary of State];

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- (c) if they are made by an enforcement authority in Scotland other than the Secretary of State, shall be arrangements approved by the Secretary of State;

and any such arrangements as are mentioned in paragraph 15(b) of this Schedule, if made by [<sup>F4</sup>the Pharmaceutical Society of Northern Ireland] in Northern Ireland, shall be arrangements approved by [<sup>F5</sup>the Minister for Health, Social Services and Public Safety].

#### Textual Amendments

- F1** Sch. 3 para. 17(a) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 68(a)** (with regs. 2(4), 3)
- F2** Words in Sch. 3 para. 17(b) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 68(b)** (with regs. 2(4), 3)
- F3** Words substituted by virtue of [S.I. 1968/1699](#), arts. 2, 5(4)(a)
- F4** Words in [Sch. 3 para. 17](#) substituted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 34(d)(i)** (with Sch. 32)
- F5** Words in Sch. 3 para. 17 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 34(d)(ii)** (with Sch. 32)

#### Modifications etc. (not altering text)

- C1** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: [S.I. 1969/388](#), art. 2(1)

- 18 (1) Subject to the following sub-paragraph, the person to whom the sample is submitted under paragraph 15 or paragraph 16 of this Schedule shall analyse or examine the sample (as the case may be), or cause the sample to be analysed or examined by some other person under his direction, as soon as practicable.
- (2) If the person to whom the sample is so submitted is a public analyst, and that analyst determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to the public analyst for some other area, and that other public analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.
- 19 (1) A public analyst who has analysed a sample submitted to him under the preceding provisions of this Schedule, or who has caused such a sample to be analysed by some other person under his direction, shall issue and send to the sampling officer a certificate specifying the result of the analysis.
- (2) A person having the management or control of a laboratory in which a sample submitted to him under the preceding provisions of this Schedule has been analysed or examined, or a person appointed by him for the purpose, shall issue and send to the sampling officer a certificate specifying the result of the analysis or examination.
- (3) Any certificate issued under this paragraph shall be in a form prescribed by the Ministers and shall be signed by the person who issues the certificate.
- 20 (1) Any person to whom, in accordance with paragraphs 2 to 8 of this Schedule, a part of the sample is required to be supplied shall, on payment of the prescribed fee to the relevant enforcement authority, be entitled to be supplied with a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 19 of this Schedule.

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- (2) Any regulations prescribing a fee for the purposes of this paragraph shall be made by the Ministers.

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**Changes and effects yet to be applied to the whole Act associated Parts and Chapters:**

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 69(1A)(1B) added (prosp.) by [1997 c. 19 s. 1Sch. para. 5\(b\)](#)
- s. 84B inserted by [S.I. 2016/372 art. 12](#)