

Changes to legislation: Medicines Act 1968, SCHEDULE 3 is up to date with all changes known to be in force on or before 15 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**
- C2** 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**
- C3** 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)
- C4** 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**

Introductory

- 1 (1) The provisions of this Schedule shall have effect where a person authorised in that behalf by an enforcement authority (in this Schedule referred to as a “sampling officer”) obtains a sample of any substance or article—
- (a) for the purpose of ascertaining whether there is or has been, in connection with that substance or article, any contravention of any provisions of this Act or of any regulations or order made thereunder which, by or under any provisions of sections 108 to 110 of this Act, that authority (in this Schedule referred to as “the relevant enforcement authority”) is required or empowered to enforce, or
 - (b) otherwise for any purpose connected with the performance by that authority of their functions under this Act or under any such regulations or order,
- and the sampling officer obtains the sample by purchase or in the exercise of any power conferred by section 112 of this Act.
- (2) In this Schedule “public analyst”, [^{F1}except in relation to Northern Ireland, has the meaning assigned to it by section 27 of the Food Safety Act 1990], and in relation to Northern Ireland has the meaning assigned to it by [^{F2}Article 27(1) of the Food Safety (Northern Ireland) Order 1991].

Textual Amendments

- F1** Words in Sch. 3 para. 1(2) substituted (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 12**

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F2 Words in Sch. 3 para. 1(2) substituted (N.I.) (21.5.1991) by S.I. 1991/762, art. 51(1), **Sch. 2 para.10**; S.R. 1991/175, **art. 2(1)**.

Division of sample

2 The sampling officer shall forthwith divide the sample into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit.

3 If the sample was purchased by the sampling officer, otherwise than from an automatic machine, he shall supply one part of the sample to the seller.

4 If the sampling officer obtained the sample from an automatic machine, then—
(a) if a person’s name, and an address in the United Kingdom, are stated on the machine as being the name and address of the owner of the machine, the sampling officer shall supply one part of the sample to that person;
(b) in any other case, the sampling officer shall supply one part of the sample to the occupier of the premises on which the machine stands or to which it is affixed.

F35

Textual Amendments
F3 Sch. 3 paras. 5-7 repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(a), **Sch 35** (with Sch. 32)

F36

Textual Amendments
F3 Sch. 3 paras. 5-7 repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(a), **Sch 35** (with Sch. 32)

F37

Textual Amendments
F3 Sch. 3 paras. 5-7 repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(a), **Sch 35** (with Sch. 32)

8 In any case not falling within any of paragraphs [F43 or 4] of this Schedule the sampling officer shall supply one part of the sample to the person appearing to him to be the owner of the substance or article from which the sample was taken.

Textual Amendments
F4 Words in Sch. 3 para. 8 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 34(b)** (with Sch. 32)

9 In every case falling within any of paragraphs [F53, 4, or 8] of this Schedule the sampling officer shall inform the person to whom the part of the sample in question

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is supplied that the sample has been obtained for the purpose of analysis or other appropriate examination.

Textual Amendments

F5 Words in [Sch. 3 para. 9](#) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 34\(c\)](#) (with [Sch. 32](#))

- 10 Of the remaining parts of the sample into which the sample is divided in accordance with paragraph 2 of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall—
- (a) retain one part for future comparison, and
 - (b) submit the other part for analysis or examination in accordance with the following provisions of this Schedule.
- 11 Where a sample consists of substances or articles enclosed in unopened containers, and it appears to the sampling officer that to open the containers and divide the contents into parts—
- (a) is not reasonably practicable, or
 - (b) might affect the composition or impede the proper analysis or other examination of the contents,
- the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them.
- 12 Section 127 of this Act shall have effect in relation to supplying any part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.
- 13 If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample ought to be supplied in pursuance of the preceding paragraphs, he may retain that part of the sample instead of supplying it.

Notice to person named on container

- 14 (1) Where it appears to the sampling officer that a substance or article of which he has obtained a sample was manufactured or assembled by a person whose name and address in the United Kingdom are stated on its container, and who is not a person to whom a part of the sample is required to be supplied under the preceding provisions of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall serve notice on that person—
- (a) stating that the sample has been obtained by the sampling officer, and
 - (b) specifying the person from whom the sampling officer purchased it, or, if he obtained it otherwise than by purchase, the place from which he obtained it.
- (2) The notice required to be served under the preceding sub-paragraph shall be served before the end of the period of three days beginning with the day on which the sample was obtained.

Analysis or other examination of sample

- 15 If the sampling officer decides to submit the sample for analysis or other appropriate examination, he shall—

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- (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,—
- ^{F6}(a)
- (b) if ^{F7}... they are made by an enforcement authority in England and Wales other than [^{F8}the Secretary of State], shall be arrangements approved by [^{F8}the Secretary of State];
- (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 [^{F9}the Pharmaceutical Society of Northern Ireland] in Northern Ireland, shall be arrangements approved by [^{F10}the Minister for Health, Social Services and Public Safety].

Textual Amendments

- F6** 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)
- F7** 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)
- F8** Words substituted by virtue of [S.I. 1968/1699](#), [arts. 2, 5\(4\)\(a\)](#)
- F9** 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)
- F10** 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)

- C5** 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

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

Provisions as to evidence

- 21 In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 19 of this Schedule shall be sufficient evidence of the facts stated in the document, unless the other party requires that the person who issued the certificate shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.
- 22 In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings, which has been supplied to him by the other party as being a copy of such a certificate, shall be sufficient evidence of the facts stated in the document.
- 23 (1) If in any such proceedings before a magistrates' court a defendant intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, a notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the other party at least three clear days before the day on which the summons is returnable.
- (2) If the preceding sub-paragraph is not complied with, the court may, if it thinks fit, adjourn the hearing on such terms as it thinks proper.
- (3) In Scotland, if in any such proceedings in the sheriff court the accused intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the procurator fiscal at least three clear days before the day on which the case proceeds to trial.
- (4) If sub-paragraph (3) of this paragraph is not complied with, the sheriff may, if he thinks fit, adjourn the diet on such terms as he deems proper.

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Analysis under direction of court

- 24 (1) In any proceedings for an offence under this Act, where the proceedings relate to a substance or article of which a sample has been obtained as mentioned in paragraph 1 of this Schedule, the part of the sample retained in pursuance of paragraph 10(a) of this Schedule shall be produced as evidence; and the court—
- (a) at the request of either party to the proceedings shall, and
 - (b) in the absence of any such request may if it thinks fit,
- cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, the Government Chemist for Northern Ireland) or to be sent for other appropriate examination to the person having the management or control of a laboratory specified by the court.
- (2) If, in a case where an appeal is brought, no action has been taken under the preceding sub-paragraph, the provisions of that sub-paragraph shall have effect in relation to the court by which the appeal is heard.
- (3) A person to whom a part of a sample is sent under this paragraph for analysis or other examination shall analyse or examine it, or cause it to be analysed or examined on his behalf, and shall transmit to the court a certificate specifying the result of the analysis or examination.
- (4) Any such certificate shall be signed by that person, or signed on his behalf by the person who made the analysis or examination or a person under whose direction it was made.
- (5) Any such certificate shall be evidence (and, in Scotland, shall be sufficient evidence) of the facts stated in the certificate unless any party to the proceedings requires that the person by whom it was signed shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.
- 25 The costs of any analysis or examination under paragraph 24 of this Schedule shall be paid by the prosecutor or the defendant (or, in Scotland, the accused) as the court may order.

Proof by written statement

- 26 In relation to England and Wales section 9 of the ^{M1}Criminal Justice Act 1967, and in relation to Northern Ireland any corresponding enactment which may be passed by the Parliament of Northern Ireland, shall not have effect with respect to any document produced as mentioned in paragraph 21 or paragraph 22 of this Schedule or with respect to any certificate transmitted to a court under paragraph 24 of this Schedule.

Marginal Citations

M1 1967 c. 80.

Power to modify sampling provisions

- 27 The Ministers may by order provide that, in relation to substances or articles of any such description as may be specified in the order, the preceding provisions of this

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Schedule shall have effect subject to such exceptions and modifications as may be specified in the order.

Payment for sample taken under compulsory powers

- 28 (1) Where a sampling officer takes a sample in the exercise of any power conferred by section 112 of this Act he shall, if payment is demanded, pay the value of the sample to the person to whom a part of the sample is required under paragraph 5, paragraph 7 or paragraph 8 of this Schedule (as the case may be) to be supplied.
- (2) In default of agreement between the sampling officer and the person mentioned in the preceding sub-paragraph, the value of the sample shall be determined by the arbitration of a single arbitrator appointed by the sampling officer and the other person in question or, if they are unable to agree on the appointment of an arbitrator, shall be determined by the county court^[F11] for the district (or, in Northern Ireland, the division) in which the sample was taken].
- [^{F12}(2A) For the purposes of this paragraph, England and Wales is to be treated as the district of the county court in England and Wales.]
- (3) In the application of this paragraph to Scotland, for references to an arbitrator there shall be substituted references to an arbiter and for the reference to the county court there shall be substituted a reference to the sheriff.

Textual Amendments

- F11** Words in Sch. 3 para. 28(2) repealed (N.I.) (31.10.2016) by [Justice Act \(Northern Ireland\) 2015 \(c. 9\)](#), s. 106(2), Sch. 1 para. 60, [Sch. 9 Pt. 1](#) (with Sch. 8 para. 1); S.R. 2016/387, art. 2(k)(m) (with art. 3)
- F12** Sch. 3 para. 28(2A) inserted (22.4.2014) by [Crime and Courts Act 2013 \(c. 22\)](#), s. 61(3), [Sch. 9 para. 111](#); S.I. 2014/954, art. 2(c) (with art. 3) (with transitional provisions and savings in S.I. 2014/956, arts. 3-11)

Application of s. 64 to samples

- 29 Where a medicinal product is taken as a sample by a sampling officer in the exercise of any power conferred by section 112 of this Act, the provisions of subsections (1) to (4) of section 64 of this Act shall have effect as if the taking of the product as a sample were a sale of it to the sampling officer by the person from whom it is taken; and, if the product was prepared in pursuance of a prescription given by a practitioner, those provisions shall so have effect as if, in subsection (1) of that section, for the words “demanded by the purchaser”, there were substituted the words “specified in the prescription”

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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](#)