Medicines Act 1968

1968 CHAPTER 67

PART III

FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

Offences, and provision for disqualification

67 Offences under Part III.

(1) The following provisions of this section shall have effect subject to sections 121 and 122 of this Act.

[F1(1A) Any person who gives a prescription or directions or administers a medicinal product in contravention of a condition imposed by an order under section 58 of this Act by virtue of subsection (4A) of that section shall be guilty of an offence.

(1B) Any person who—

(a) is an appropriate practitioner **[**F2 within the meaning of regulation 214 of the 2012 Regulations**]** ; and

(b) gives a prescription or directions in respect of a medicinal product of a description or class in relation to which he is not an appropriate practitioner,

shall be guilty of an offence.**]**

(2) Any person who contravenes any of the following provisions of this Part of this Act, that is to say, sections **[**F3 63 and 64**]**, or who contravenes F4... any order made under section 62 of this Act, shall be guilty of an offence.

(3) Where a medicinal product is sold, supplied or imported in contravention of an order made under section 62 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the medicinal product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, shall be guilty of an offence.

F5(3A) . . . . . .

(4) Any person guilty of an offence under **[**F6subsection (1A), (1B), (2) or (3)**]** of this section shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

F7(5) . . . . . .

F7(6) . . . . . .

Textual Amendments

F1 S. 67(1A)(1B) inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, **s. 63(7)(a)** (with ss. 64(9), 65(4)); S.I. 2002/1095, **art. 2(1)** (with transitional provisions in art. 3)

F2 Words in s. 67(1B)(a) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(2)** (with Sch. 32)

F3 Words in s. 67(2) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(3)(a)** (with Sch. 32)

F4 Words in s. 67(2) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(3)(b)** (with Sch. 32)

F5 S. 67(3A) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 9(4), **Sch. 35** (with Sch. 32)

F6 Words in s. 67(4) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(5)** (with Sch. 32)

F7 S. 67(5)(6) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 9(6), **Sch. 35** (with Sch. 32)

Modifications etc. (not altering text)

C1 S. 67 extended by S.I.s 1982/425, art. 3, 1984/187, art. 2 and extended with modifications by S.I. 1985/1403, **art. 3(1)**
S. 67 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**
S. 67 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch. 5**

[F8**67A. Defence to offence of contravening section 63(a) or (b): product not sold or supplied**

(1) This section applies in a case where—

(a) a person ("the defendant") is charged with an offence under section 67(2) of contravening section 63(a) or (b) in respect of a medicinal product; and

(b) the product is not sold or supplied in its adulterated state.

(2) Where the defendant is charged with contravening section 63(a), it is a defence for the defendant to prove that—

[F9(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;**]**

(b) the defendant—

(i) was a registrant acting in the course of his or her profession, or

(ii) was acting under the supervision of a person who was a registrant acting in the course of his or her profession; and

(c) at the time of the alleged contravention, the defendant did not know that the product was being adulterated.

(3) Where the defendant is charged with contravening section 63(b), it is a defence for the defendant to prove that—

[[F10](a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;**]**

(b) the person who adulterated the product—

(i) was a registrant acting in the course of his or her profession, or

(ii) was acting under the supervision of a person who was a registrant acting in the course of his or her profession; and

(c) at the time of the alleged contravention, the defendant did not know that the product had been adulterated.

Textual Amendments

F8 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F9 S. 67A(2)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **5(2)** (with art. 3); S.I. 2022/1024, art. 2

F10 S. 67A(3)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **5(3)** (with art. 3); S.I. 2022/1024, art. 2

67B. Defence to offence of contravening section 63(a) or (b): product sold or supplied

(1) This section applies in a case where—

(a) a person ("the defendant") is charged with an offence under section 67(2) of contravening section 63(a) or (b) in respect of a medicinal product; and

(b) the product was sold or supplied in its adulterated state.

(2) It is a defence for the defendant to prove that—

[[F11](a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;**]**

(b) the person who adulterated the product—

(i) was a registrant acting in the course of his or her profession, or

(ii) was acting under the supervision of a person ("the supervising registrant") who was a registrant acting in the course of his or her profession;

(c) the product was—

(i) sold or supplied in pursuance of a prescription or directions given by a relevant prescriber or a patient group direction, or

(ii) a prescription only medicine that was sold or supplied in circumstances where there was an immediate need for it to be sold or supplied and a prescription could not have been obtained without undue delay; and

(d) Condition A or B is met.

(3) Condition A is that before the defendant was charged—

(a) the defendant did not know that the product had been adulterated; and

(b) if the defendant is a person within subsection (4), neither the person who adulterated the product nor (in a case within subsection (2)(b)(ii)) the supervising registrant knew that the product had been adulterated.

(4) A defendant is a person within this subsection if the defendant is any of the following—

(a) the person who adulterated the product;

(b) (in a case within subsection (2)(b)(ii)) the supervising registrant;

(c) the person carrying on the retail pharmacy business **[**F12, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied.

(5) Condition B is that—

(a) before the defendant was charged, an appropriate person, on becoming aware that the product had been adulterated—

(i) promptly ensured that all reasonable steps were taken to ensure that the person to whom the product was intended to be administered was notified that the product had been adulterated, or

(ii) reasonably formed the view that it was not necessary or appropriate to do so, in the circumstances of the case; and

(b) the defendant did not know at the time that the product was sold or supplied that it had been adulterated.

(6) In subsection (5), "appropriate person" means any of the following—

(a) the person who adulterated the product or (in a case within subsection (2)(b)(ii)) the supervising registrant;

(b) the person carrying on the retail pharmacy business **[**F13, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied, or any person acting on that person's behalf.

Textual Amendments

F8 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F11 S. 67B(2)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **6(2)** (with art. 3); S.I. 2022/1024, art. 2

F12 Words in s. 67B(4)(c) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **6(3)** (with art. 3); S.I. 2022/1024, art. 2

F13 Words in s. 67B(6)(b) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **6(4)** (with art. 3); S.I. 2022/1024, art. 2

67C. Defence to offence of contravening section 64

(1) This section applies in a case where a person ("the defendant") is charged with an offence under section 67(2) of contravening section 64 in respect of a medicinal product.

(2) It is a defence for the defendant to prove that—

[F14(a) the product was dispensed—

(i) at or from a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;**]**

(b) the person who dispensed the product—

(i) was a registrant acting in the course of his or her profession, or

(ii) was acting under the supervision of a person ("the supervising registrant") who was a registrant acting in the course of his or her profession;

(c) the product was—

(i) sold or supplied in pursuance of a prescription or directions given by a relevant prescriber or a patient group direction, or

(ii) a prescription only medicine that was sold or supplied in circumstances where there was an immediate need for it to be sold or supplied and a prescription could not have been obtained without undue delay; and

(d) Condition A or B is met.

(3) Condition A is that before the defendant was charged—

(a) the defendant did not know that the product was not of the required nature or quality; and

(b) if the defendant is a person within subsection (4), neither the person who dispensed the product nor (in a case within subsection (2)(b)(ii)) the supervising registrant knew that the product was not of the required nature or quality.

(4) A defendant is a person within this subsection if the defendant is any of the following—

(a) the person who dispensed the product;

(b) (in a case within subsection (2)(b)(ii)) the supervising registrant;

(c) the person carrying on the retail pharmacy business **[**F15, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied.

(5) Condition B is that—

(a) before the defendant was charged, an appropriate person, on becoming aware that the product was not of the required nature or quality—

(i) promptly ensured that all reasonable steps were taken to ensure that the person to whom the product was intended to be administered was notified that the product was not of the required nature or quality, or

(ii) reasonably formed the view that it was not necessary or appropriate to do so, in the circumstances of the case; and

(b) the defendant did not know at the time the product was sold or supplied that it was not of the required nature or quality.

(6) In subsection (5), "appropriate person" means any of the following—

(a) the person who dispensed the product or (in a case within subsection (2)(b)(ii)) the supervising registrant;

(b) the person carrying on the retail pharmacy business **[**F16, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied, or any person acting on that person's behalf.

(7) In this section, "the required nature or quality", in relation to a product, means—

(a) where the product is sold or supplied in pursuance of a prescription, the nature or quality specified in the prescription; or

(b) in any other case, the nature or quality demanded by the purchaser of the product.

Textual Amendments

F8 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F14 S. 67C(2)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **7(2)** (with art. 3); S.I. 2022/1024, art. 2

F15 Words in s. 67C(4)(c) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **7(3)** (with art. 3); S.I. 2022/1024, art. 2

F16 Words in s. 67C(6)(b) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **7(4)** (with art. 3); S.I. 2022/1024, art. 2

67D. Defences under sections 67A, 67B and 67C: evidence etc.

(1) This section applies for the purposes of sections 67A to 67C.

(2) If evidence is adduced that is sufficient to raise an issue with respect to the doing of an act by a person in the course of his or her profession, the court must assume that the person did that act in the course of his or her profession unless the prosecution proves the contrary beyond reasonable doubt.

(3) The court must assume that the prosecution has proved the contrary beyond reasonable doubt if the prosecution proves beyond reasonable doubt that, in doing that act—

(a) the person used his or her professional skills for an improper purpose; or

(b) the person deliberately failed to have due regard for patient safety.

(4) Proof that a registrant failed to comply with a procedure established in relation to a registered pharmacy **[**F17or a relevant pharmacy service**]** does not of itself constitute proof that the registrant was not acting in the course of his or her profession.

(5) Knowledge acquired after a product is sold or supplied does not count if it is acquired only as a result of an investigation into whether an offence has been committed in respect of a product.

(6) If evidence is adduced that is sufficient to raise an issue with respect to doing of an act promptly, the court must assume that the act was done promptly unless the prosecution proves the contrary beyond reasonable doubt.

(7) A medicinal product is taken to be sold or supplied to a person in pursuance of a prescription or direction even if that person is not the person for whom it was dispensed in pursuance of the prescription or direction.

Textual Amendments

F8 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F17 Words in s. 67D(4) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **8** (with art. 3); S.I. 2022/1024, art. 2

67E. Sections 67A to 67D: [F18"adulteration" and "registrant"]

In sections 67A to 67D—

"adulteration", in relation to a medicinal product, means the addition of a substance to, or the abstraction of a substance from, the product, so as to affect injuriously its composition (and related expressions are to be construed accordingly);

"registrant" means—

(a) where it is alleged that the offence in question took place in Great Britain, a person who is entered in Part 1, **[**F19or 2**]** of the register of pharmacists and pharmacy technicians established and maintained under article 19 of the Pharmacy Order 2010 (SI 2010/231); or

(b) where it is alleged that the offence in question took place in Northern Ireland, a person registered in the register of pharmaceutical chemists for Northern Ireland F20... maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 (SI 1976/1213 (NI 22)).**]**

Textual Amendments

F8 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F18 Words in s. 67E heading substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **9(2)** (with art. 3); S.I. 2022/1024, art. 2

F19 Words in s. 67E substituted (31.12.2020) by The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 3(a)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

F20 Words in s. 67E omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 3(b)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

[F21 67F Sections 67A to 67D: "relevant pharmacy service"

(1) For the purposes of sections 67A to 67D a pharmacy service is a relevant pharmacy service if conditions A and B are met in respect of it.

(2) Condition A is met in respect of a pharmacy service if—

(a) the service is provided in England by a person in the course of carrying on a regulated activity in respect of which the person is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008;

(b) the service is provided in Wales—

(i) in the course of the business of a hospital,

(ii) in a prison or youth detention accommodation within the meaning of sections 185 to 187 of the Social Services and Well-being (Wales) Act 2014 (anaw 4) (see section 188 of that Act),

(iii) in a removal centre, short-term holding facility or pre-departure accommodation within the meaning of Part 8 of the Immigration and Asylum Act 1999 (see section 147 of that Act),

(iv) by a person in the course of carrying on or managing an establishment in respect of which the person is registered under Part 2 of the Care Standards Act 2000, or

(v) by a person in the course of providing a regulated service in respect of which the person is registered under Chapter 2 of Part 1 of the Regulation and Inspection of Social Care (Wales) Act 2016 (anaw 2);

(c) the service is provided in Scotland—

(i) in the course of the business of a hospital,

(ii) in a prison within the meaning of section 49C of the Criminal Law (Consolidation) (Scotland) Act 1995 (see subsection (7) of that section),

(iii) in a removal centre, short-term holding facility or pre-departure accommodation within the meaning of Part 8 of the Immigration and Asylum Act 1999 (see section 147 of that Act),

(iv) by a person in the course of providing an independent health care service which is registered under section 10P of the National Health Service (Scotland) Act 1978, or

(v) by a person in the course of carrying on a care service which is registered under Chapter 3 of Part 5 of the Public Services Reform (Scotland) Act 2010 (asp 8); or

(d) the service is provided in Northern Ireland—

(i) in the course of the business of a hospital,

(ii) in a prison or other institution for the treatment of offenders, including a place mentioned in section 2 of the Treatment of Offenders Act (Northern Ireland) 1968 (c. 29 (N.I.)) and a juvenile justice centre within the meaning of the Criminal Justice (Children) (Northern Ireland) Order 1998 (S.I. 1998/1504 (N.I. 9)) (see Article 51(1) of that Order),

(iii) in a removal centre, short-term holding facility or pre-departure accommodation within the meaning of Part 8 of the Immigration and Asylum Act 1999 (see section 147 of that Act), or

(iv) by a person in the course of carrying on or managing an establishment in respect of which the person is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 (S.I. 2003/431 (N.I. 9)).

(3) Condition B is met in respect of a pharmacy service if it has a chief pharmacist.

(4) A chief pharmacist, in relation to a pharmacy service, is a pharmacist who—

(a) plays a significant role (irrespective of whether other individuals also do so) in—

(i) the making of decisions about how the whole or a substantial part of the activities of the pharmacy service are to be managed or organised, or

(ii) the actual managing or organising of the whole or a substantial part of those activities,

(b) has the authority to make decisions that affect the running of the pharmacy service so far as concerns the sale or supply of medicinal products, and

(c) is responsible for securing that the pharmacy service is carried on safely and effectively.

(5) For the purposes of subsection (4)(c) a pharmacy service is carried on safely and effectively if it is carried on in ways that ensure its safe and effective running so far as concerns the sale or supply of medicinal products.**]**

Textual Amendments

F21 S. 67F inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **9(1)** (with art. 3); S.I. 2022/1024, art. 2

F22 68 Disqualification on conviction of certain offences.

. . . . . .

Textual Amendments

F22 S. 68 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Status:
Point in time view as at 01/12/2022.

Changes to legislation:
Medicines Act 1968, Cross Heading: Offences, and provision for disqualification is up to date with all changes known to be in force on or before 07 July 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.