Draft Order in Council laid before Parliament under section 62(9) of the Health Act 1999, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2018 No. 000

MEDICINES

HEALTH CARE AND ASSOCIATED PROFESSIONS

The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018

Made - - - - 2018

Coming into force in accordance with article 1

At the Court at Buckingham Palace, the day of

Present,

The Queen's Most Excellent Majesty in Council

This Order in Council is made in exercise of the powers conferred by sections 60(1)(a) and (2A)(c) and 62(4) and (4A) of, and paragraphs 1(e), 2 and 3 of Schedule 3 to, the Health Act 1999(**a**).

The Secretary of State published a draft of this Order in Council and invited representations as required by paragraph 9(1) of Schedule 3 to the Health Act 1999.

The period of three months mentioned in paragraph 9(2) of that Schedule expired before a draft of this Order in Council, together with a report about the consultation, was laid before Parliament.

A draft of this Order in Council has been approved by resolution of each House of Parliament in accordance with section 62(9) of the Health Act 1999.

(**a**) 1999 c. 8. Section 60 has been amended by: the National Health Service Reform and Health Care Professions Act 2002 (c. 17) ("the 2002 Act"), section 26(9); the Health and Social Care Act 2008 (c. 14) ("the 2008 Act"), Schedule 8, paragraph 1, and Schedule 10, paragraph 10; the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), sections 209, 210 and 213(7)(i), and Schedule 15, paragraphs 60 and 72(2); and S.I. 2002/253 and 254, 2010/231 and 2012/1916. Section 62 has been amended by: the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraphs 194 and 197, and Schedule 4, paragraph 1; and the 2008 Act, Schedule 8, paragraph 2, and Schedule 10, paragraph 11. Schedule 3 has been amended by: the 2002 Act, section 26(10); the Health and Social Care (Community Health and Standards) Act 2003 (c. 43), Schedule 11, paragraph 67, and Schedule 14, Part 4; the Health Act 2006 (c. 28), section 33 and Schedule 9; the 2008 Act, Schedule 8, paragraphs 3 to 10; the 2012 Act, section 211 and Schedule 15, paragraphs 61 and 72(4); and S.I. 2002/254.

Accordingly, Her Majesty is pleased, by and with the advice of Her Privy Council, to make the following Order in Council:

PART 1

Introductory

Citation and commencement

1.—(1) This Order may be cited as the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018.

(2) This Order, apart from article 4, comes into force on the twenty-eighth day after the day on which this Order is made.

(3) Article 4 comes into force on such days as the Privy Council may by order appoint.

(4) Different days may be appointed under paragraph (3) for different purposes.

Transitional and saving provisions

2.—(1) In connection with the commencement of article 4, the Privy Council may by order make such transitional or saving provisions as it considers appropriate.

(2) The power to make an order under paragraph (1) may be exercised—

(a) so as to make different provision—

(i) for different areas,

(ii) with respect to different cases or different classes of cases, and

(iii) in respect of the same case or class of case for different purposes;

(b) in relation to all cases to which the power extends or in relation to those cases subject to specified exceptions; and

(c) so as to make any supplementary, incidental or consequential provisions which the Privy Council considers necessary or expedient.

Privy Council procedures and legislative procedures

3.—(1) Any power vested in the Privy Council to make an order under this Part may be exercised by any two or more members of the Privy Council.

(2) Any power of the Privy Council to make an order under this Part is exercisable by statutory instrument, and for the purposes of section 1 of the Statutory Instruments Act 1946(**a**) (definition of "Statutory Instrument"), any power of the Privy Council to make an order under this Part is to be taken to be conferred by an Act of Parliament.

(3) An order made (wholly or partly) under article 2(1) is subject to annulment by resolution of either House of Parliament.

(4) Before making an order under article 1(3) that commences an amendment of the Medicines Act 1968(**b**) as it applies in Northern Ireland, the Privy Council must obtain the agreement of the Department of Health in Northern Ireland to the making of the order.

(5) Any act of the Privy Council under this Part is sufficiently signified by an instrument signed by the Clerk of the Privy Council.

(**a**) 1946 c. 36. Section 1(1A) was inserted by the Government of Wales Act 1998 (c. 38), Schedule 12, paragraph 2, and substituted by the Government of Wales Act 2006 (c. 32), Schedule 10, paragraph 2.

(**b**) 1968 c. 67.

(6) Where an order of the Privy Council under this Part is signified by an instrument purporting to be signed by the Clerk of the Privy Council, that is evidence and in Scotland sufficient evidence of—

(a) the fact that the order was duly made; and

(b) the order's terms.

PART 2

Amendment of the Medicines Act 1968

New defences to the offences of contravening sections 63 and 64 of the Medicines Act 1968, and related provisions

4. In Part 3 of the Medicines Act 1968(**a**) (further provisions relating to dealings with medicinal products), after section 67 (offences under Part 3), insert—

"**Defence to offence of contravening section 63(a) or (b): product not sold or supplied**

67A.—(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—

(a) the adulteration took place at a registered pharmacy;

(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—

(a) the adulteration took place at a registered pharmacy;

(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.

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

67B.—(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.

(**a**) 1968 c. 67.

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

(a) the adulteration took place at a registered pharmacy;

(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(**a**), 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 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 in the course of which the product was sold or supplied, or any person acting on that person's behalf.

Defence to offence of contravening section 64

67C.—(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—

(**a**) *See* regulation 213 of the Human Medicines Regulations 2012 (S.I. 2012/1916), which contains definitions of "relevant prescriber" and "patient group direction" which, by virtue of section 132(1) of the Medicines Act 1968 (c. 67), are the definitions of those expressions that apply for the purposes of that Act.

(a) the product was dispensed at a registered pharmacy;

(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 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 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.

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

67D.—(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 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.

Sections 67A to 67D: interpretation

67E. 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, 2, 4 or 5 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 or the register of visiting pharmaceutical chemists for a relevant European State maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 (SI 1976/1213 (NI 22)).".

Name
Clerk of the Privy Council

EXPLANATORY NOTE

(This note is not part of the Order)

This Order includes new defences relating to preparation errors and dispensing errors by registered pharmacists and registered pharmacy technicians, or persons supervised by them, at retail pharmacy premises. Retail pharmacy premises in the United Kingdom have to be registered by either the General Pharmaceutical Council or the Pharmaceutical Society of Northern Ireland – by virtue of provisions of Part 4 of the Medicines Act 1968. Pharmacy technicians are not statutorily registered in Northern Ireland, and so, as regards Northern Ireland, the new defences only apply to preparation errors and dispensing errors by registered pharmacists and persons supervised by them.

Articles 1 to 3 contain general provisions, including powers to make commencement orders and transitional provisions orders – and the procedural requirements relating to them.

Article 4 contains amendments to the Medicines Act 1968 creating new defences to offences of contravening sections 63 and 64 of that Act, and dealing with supplementary matters.

The offences in section 63 relate to adulteration of medicinal products for human use. If the product is not sold or supplied, in order to benefit from the new defence in section 67A, the defendant must prove three things. Firstly, the person who adulterated the product either was a registered pharmacist or registered pharmacy technician who was acting in the course of his or her profession, or was acting under the supervision of such a registrant. Secondly, the adulteration took place at a registered pharmacy. Thirdly, the defendant did not know that the product was being – or (if it was being offered or exposed for sale or supply) had been – adulterated.

If the product is actually sold or supplied, in order to benefit from the new defence in section 67B, in most cases the defendant must prove four things. Firstly, the person who adulterated the product either must have been a registered pharmacist or registered pharmacy technician who was acting in the course of his or her profession, or must have been acting under the supervision of such a registrant. Secondly, the adulteration must have taken place at a registered pharmacy. Thirdly, the product must have been sold or supplied in pursuance of a prescription or directions, or be an emergency sale or supply of a prescription only medicine in circumstances where a prescription could not be obtained without undue delay. Fourthly, if an appropriate person (such as the dispenser) becomes aware of the mistake, all reasonable steps must be taken to ensure that the patient is notified of the mistake, unless the appropriate person reasonably forms the view that it is neither necessary nor appropriate to do so.

The offence in section 64 relates to the sale, or supply in pursuance of a prescription, of medicinal products for human use which are not of the nature or quality demanded by the purchaser or as specified in a prescription. The elements of the new defence in section 67C which apply in most cases are similar to those in the new section 67B. Firstly, the person who dispensed the product either must have been a registered pharmacist or registered pharmacy technician who was acting in the course of his or her profession, or must have been acting under the supervision of such a registrant. Secondly, the dispensing of the product must have taken place at a registered pharmacy. Thirdly, the sale or supply must have been in pursuance of a prescription – or possibly directions, in the case of a sale – or be an emergency supply of a prescription only medicine in circumstances where a prescription could not be obtained without undue delay. Fourthly, if an appropriate person (such as the dispenser) becomes aware of the mistake, all reasonable steps must be taken to ensure that the patient is notified of the mistake, unless the appropriate person reasonably forms the view that it is neither necessary nor appropriate to do so.

There are also new provisions in section 67D and 67E relating to rules of evidence and interpretation in respect of the new defences, and these include a rule that a registered pharmacist or registered pharmacy technician is not to be considered as acting in the course of his or her profession for the purposes of the new defences if he or she either misuses his or her professional skills for an improper purpose or deliberately fails to have due regard for patient safety.

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health, Wellington House, 133-155 Waterloo Road, London SE1 8UG. It is also available alongside this instrument on www.legislation.gov.uk.

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