DRAFT STATUTORY INSTRUMENTS

2018 No.

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

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(**1**) (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.

(**1**) 1968 c. 67.

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.

(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(**2**), 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—

(**2**) *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 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) 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)).".