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DRAFT STATUTORY INSTRUMENTS

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**2022 No.**

**The Pharmacy (Preparation and Dispensing Errors –  
Hospital and Other Pharmacy Services) Order 2022**

**PART 2**

**Amendment of the Medicines Act 1968**

**Amendment of section 67A of the 1968 Act**

**5.**—(1) Section 67A of the 1968 Act<sup>(1)</sup> (defence to offence of contravening section 63(a) or (b): product not sold or supplied) is amended as follows.

(2) In subsection (2), for paragraph (a) substitute—

“(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;”.

(3) In subsection (3), for paragraph (a) substitute—

“(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;”.

**Amendment of section 67B of the 1968 Act**

**6.**—(1) Section 67B of the 1968 Act<sup>(2)</sup> (defence to offence of contravening section 63(a) or (b): product sold or supplied) is amended as follows.

(2) In subsection (2), for paragraph (a) substitute—

“(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;”.

(3) In subsection (4), in paragraph (c), after “retail pharmacy business” insert “, or the relevant pharmacy service,”.

(4) In subsection (6), in paragraph (b), after “retail pharmacy business” insert “, or the relevant pharmacy service,”.

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(1) Section 67A was inserted by [S.I. 2018/181](#).

(2) Section 67B was inserted by [S.I. 2018/181](#).

### **Amendment of section 67C of the 1968 Act**

7.—(1) Section 67C of the 1968 Act<sup>(3)</sup> (defence to offence of contravening section 64) is amended as follows.

(2) In subsection (2), for paragraph (a) substitute—

- “(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;”.

(3) In subsection (4), in paragraph (c), after “retail pharmacy business” insert “, or the relevant pharmacy service,”.

(4) In subsection (6), in paragraph (b), after “retail pharmacy business” insert “, or the relevant pharmacy service,”.

### **Amendment of section 67D of the 1968 Act**

8. In section 67D of the 1968 Act<sup>(4)</sup> (defences under sections 67A, 67B and 67C: evidence etc) in subsection (4), after “pharmacy” insert “or a relevant pharmacy service”.

### **New section 67F of the 1968 Act**

9.—(1) After section 67E of the 1968 Act<sup>(5)</sup> (sections 67A to 67D: interpretation) insert—

#### **“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<sup>(6)</sup>;
- (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<sup>(7)</sup>),
  - (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<sup>(8)</sup> (see section 147 of that Act<sup>(9)</sup>),

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(3) Section 67C was inserted by [S.I. 2018/181](#).

(4) Section 67D was inserted by [S.I. 2018/181](#).

(5) Section 67E was inserted by [S.I. 2018/181](#) and amended by [S.I. 2019/593](#).

(6) [2008 c. 14](#).

(7) Section 188 has been amended by: the Criminal Justice and Courts Act 2015 ([c. 2](#)), Schedule 9, paragraph 32; the Regulation and Inspection of Social Care (Wales) Act 2016 ([anaw 2](#)), Schedule 3, Part 1; and the Sentencing Act 2020 ([c. 17](#)), Schedule 24, paragraph 32.

(8) [1999 c. 33](#).

(9) Section 147 has been amended by: the Nationality, Immigration and Asylum Act 2002 ([c. 41](#)), sections 62(14) and 66(1) to (3)(a), and Schedule 9; the Borders, Citizenship and Immigration Act 2009 ([c. 11](#)), section 25; and the Immigration Act 2014 ([c. 22](#)), section 6(1) and (2).

- (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<sup>(10)</sup>, 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<sup>(11)</sup> (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<sup>(12)</sup>, 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<sup>(13)</sup> (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,

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<sup>(10)</sup> 2000 c. 14.

<sup>(11)</sup> 1995 c. 39. Section 49C was inserted by the Custodial Sentences and Weapons (Scotland) Act 2007 (asp 17), section 63, and amended by the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13), section 37(1) and (5), and the Criminal Justice (Scotland) Act 2016 (asp 1), section 84(1) and (5).

<sup>(12)</sup> 1978 c. 29. Section 10P was inserted by the Public Services Reform (Scotland) Act 2010 (asp 8), section 108.

<sup>(13)</sup> Section 2 has been amended by S.I. 1989/1344 (N.I. 15), 1998/1504 (N.I. 9) and 2005/1965 (N.I. 15).

(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.”.

(2) In consequence of paragraph (1), in section 67E of the 1968 Act (interpretation of sections 67A to 67D), in the heading, for “interpretation” substitute ““adulteration” and “registrant””.