
DRAFT STATUTORY INSTRUMENTS

2010 No.

The Pharmacy Order 2010

PART 3

Registered Pharmacies: Standards in retail pharmacies

Standards: general

7.—(1) In the exercise of its functions under article 4(3)(b), the Council must make provision in rules about the standards that are to be met in connection with the carrying on of a retail pharmacy business at a registered pharmacy.

(2) Those standards may relate to requirements that are to be met—

- (a) by the person carrying on the retail pharmacy business; or
- (b) by a superintendent pharmacist.

(3) The standards may, in particular, relate to—

- (a) record keeping;
- (b) standard operating procedures;
- (c) the training of staff;
- (d) incident reporting mechanisms;
- (e) arrangements for the obtaining, keeping, handling, use and security of medicinal products or medical devices;
- (f) the conditions in which medicinal products (including controlled drugs) are to be stored;
- (g) the condition of the premises (including the physical state, safety and security of the premises);
- (h) the availability or condition of facilities or equipment at the premises used to carry out certain activities (including the conducting of clinical procedures (such as the taking of blood), the undertaking of consultations with patients and the carrying on of activities to which section 10 of the Medicines Act 1968⁽¹⁾ (exemptions for pharmacists) applies);
- (i) the management of waste (including the adequate procedures for the safe destruction and disposal of medicinal products kept on the premises); and
- (j) the use of the premises as a training establishment.

(4) The Council must also make provision in rules—

- (a) requiring any person carrying on a retail pharmacy business to provide information to the Council;
- (b) for such information to be provided—
 - (i) at the request of the Council, or

⁽¹⁾ 1968 c.67. Section 10 was amended by paragraph 5 of Schedule 3 to the Regulation of Care (Scotland) Act 2001 (asp 8) and by S.I.1971/1445, 1993/384, 1994/2987 and 2006/2407.

- (ii) on such dates or at such intervals as the Council may determine, either generally or in relation to particular persons carrying on a retail pharmacy business or such persons of a particular description; and
- (c) in respect of—
 - (i) the form and manner in which such information is to be provided to the Council, and
 - (ii) the time within which such information is to be provided to the Council pursuant to a request under sub-paragraph (b)(i).
- (5) Rules under paragraph (4) must, in particular, enable the Council to obtain the following information—
 - (a) details of the person carrying on the retail pharmacy business including—
 - (i) where the business is carried on by an individual, details of the home address in the Register of that individual,
 - (ii) where the business is carried on by a partnership, details of the address of the principal office of the partnership and of the names and home addresses of the partners in the partnership,
 - (iii) where the business is carried on by a body corporate, details of the address of the registered or principal office of the body corporate and of the names and home addresses of its directors;
 - (b) a list of all premises at which the retail pharmacy business is carried on;
 - (c) where medicinal products, other than medicinal products on a general sale list, are sold by retail at any premises at which a retail pharmacy business is carried on, or are supplied in circumstances corresponding to retail sale, and the retail pharmacy business is owned by a body corporate, the name of the superintendent pharmacist under whose management the business is carried on;
 - (d) details of the type or types of activities undertaken at the premises at which the retail pharmacy business is carried on; and
 - (e) details of any relevant offence or relevant investigation.
- (6) For the purposes of paragraph (5)(e)—
 - (a) a relevant offence is—
 - (i) where the retail pharmacy business is carried on by an individual, a criminal offence with which that individual has been charged,
 - (ii) where the retail pharmacy business is carried on by a partnership, a criminal offence with which any partner in the partnership has been charged,
 - (iii) where the retail pharmacy business is carried on by a body corporate, a criminal offence with which the body corporate or any of its directors has been charged,and a criminal offence is a relevant offence whether or not the charge has resulted in a caution or conviction;
 - (b) a relevant investigation is an investigation by a licensing, regulatory or other body into the conduct of—
 - (i) where the retail pharmacy business is carried on by an individual, that individual,
 - (ii) where the retail pharmacy business is carried on by a partnership, any partner in the partnership,
 - (iii) where the retail pharmacy business is carried on by a body corporate, that body corporate or any director of it,

and the reference to details of a relevant investigation includes details of the outcome of that investigation.

(7) Rules under paragraph (4) must also enable the provision to the Council of a statement which confirms that the standards that are provided for in rules made under paragraph (1) are met in connection with the carrying on of the retail pharmacy business at the registered pharmacies at which it is carried on and which is signed—

- (a) where the retail pharmacy business is carried on by an individual, by that individual;
- (b) where the retail pharmacy business is carried on by a partnership, by a partner in the partnership;
- (c) where the retail pharmacy business is carried on by a body corporate, by a director of that body corporate.