CONSULTATION DRAFT 2018/011



STATUTORY INSTRUMENTS.

S.I. No. XXX of 2018

PHARMACEUTICAL SOCIETY OF IRELAND (TEMPORARY ABSENCE OF PHARMACIST FROM PHARMACY) RULES 2018

(Prn. [•])

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PHARMACEUTICAL SOCIETY OF IRELAND (TEMPORARY ABSENCE OF PHARMACIST FROM PHARMACY) RULES 2018

The Council of the Pharmaceutical Society of Ireland, in exercise of the functions conferred on the said Society by sections 11 and 30(2) of the Pharmacy Act 2007 (*No. 20 of 2007*) (as adapted by the Health and Children (Alteration of Name of Department and Title of Minister) Order 2011 (S.I. No. 219 of 2011)), with the consent of the Minister for Health, hereby makes the following rules:-

Citation

1. These Rules may be cited as the Pharmaceutical Society of Ireland (Temporary Absence of Pharmacist from Pharmacy) Rules 2017.

Commencement

2. These Rules come into operation on xxxxxxx.

Definitions

3. In these Rules—

"Act" means the Pharmacy Act 2007 (No. 20 of 2007);

"Authority" means the Health Products Regulatory Authority;

"duty register" means the ongoing, contemporaneous and retrievable record maintained in accordance with Regulation 5(1)(c) of the Regulations;

"professional task list" means a list of professional activities normally conducted by a pharmacist which may be performed by a pharmaceutical assistant when acting in the temporary absence of a pharmacist;

"registered pharmaceutical assistant' means a person whose name is entered in the Register of Pharmaceutical Assistants kept by the Council under section 13(1)(a)(iii) of the Act;

"registered pharmacist" means a person whose name is entered in the register of pharmacists kept by the Council under section 13(1)(a)(i) of the Act;

"Regulations" means the Regulation of Retail Pharmacy Business Regulations 2008 (S.I. No. 488 of 2008);

"superintendent pharmacist" has the meaning assigned to it by Regulation 3(1) of the Regulations;

"supervising pharmacist" has the meaning assigned to it by Regulation 3(1) of the Regulations;

"temporary absence of the registered pharmacist" has the meaning assigned to it by Rule 4.

Meaning of "temporary absence of the registered pharmacist"

4. (1) Subject to paragraph (2), for the purpose of these Rules and section 30 of the Act, "temporary absence of the registered pharmacist" means any period, not exceeding one hour, during which the registered pharmacist is not physically present at the premises where a retail pharmacy business is carried on.

- (2) Where the registered pharmacist has already been absent from the premises for-
- (a) a period of one hour, or
- (b) two or more periods together amounting to one hour of absence,

on any day, any further absence that day by the registered pharmacist does not constitute "temporary absence of the registered pharmacist".

Pharmacy owners, superintendent pharmacists and supervising pharmacists

5. (1) These Rules are without prejudice to the discharge of the roles and responsibilities of the pharmacy owner, the superintendent pharmacist and the supervising pharmacist in the premises of a retail pharmacy business where a registered pharmaceutical assistant is acting on behalf of a registered pharmacist in the temporary absence of the registered pharmacist, including the duty of the pharmacy owner and the superintendent pharmacist under Regulation 5(1)(h) of the Regulations to ensure that the registered pharmaceutical assistant has the requisite knowledge, skills and fitness to so act.

(2) A pharmaceutical assistant acting on behalf of a registered pharmacist in the temporary absence of the registered pharmacist shall not act in the capacity of the superintendent pharmacist or supervising pharmacist in respect of the retail pharmacy business concerned.

Inclusion in duty register

6. The pharmacy owner and the superintendent pharmacist shall ensure that the duty register clearly indicates the period of time during which a pharmaceutical assistant is acting on behalf of a registered pharmacist in the temporary absence of the registered pharmacist.

Notification to members of public

7. The pharmacy owner and the superintendent pharmacist shall ensure that, when a registered pharmaceutical assistant acts on behalf of a registered pharmacist in the temporary absence of the registered pharmacist, steps are taken to notify any member of the public attending the premises of the retail pharmacy business that the pharmaceutical assistant is so acting.

Activities which may be carried out by pharmaceutical assistant when acting on behalf of pharmacist

8. (1) When acting on behalf of a registered pharmacist during the temporary absence of the registered pharmacist, a registered pharmaceutical assistant may carry out the following activities in addition to his or her normal activities as a registered pharmaceutical assistant:

- (a) dispensing a repeatable prescription where—
 - (i) it is not the first dispensing of the prescription, and

- (ii) the prescription is for medicinal products other than—
 - (I) high tech products,
 - (II) cytotoxic medicinal products, and
 - (III) narrow therapeutic index medications;
- (b) dispensing, or providing by sale or supply, pharmacy-only medicinal products and general sale medicinal products; and
- (c) supervising the sale or supply of pharmacy-only medicinal products and general sale medicinal products.
- (2) In this rule—

"cytotoxic medicinal products" means medicinal products that contain chemicals which are toxic to cells, preventing their replication or growth, and are used to treat cancer or malignant disease, or as an immunosuppressant;

"general sale medicinal products" means medicinal products categorised by the Authority under the sub-category referred to in Regulation 12(1)(b)(ii) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

"high tech products" means those products appearing for the time being on the list of high tech products published from time to time by the Health Service Executive;

"narrow therapeutic index medications" means medicines which, where there is a small difference in the dose or blood concentration, may lead to dose and blood concentration dependence, serious therapeutic failures or adverse drug reactions;

"pharmacy-only medicinal products" means medicinal products categorised by the Authority under the sub-category referred to in Regulation 12(1)(b)(i) of the Medicinal Products (Control of Placing on the Market) Regulations 2007;

"repeatable prescription" has the meaning assigned to it by Regulation 4(1) of the Medicinal Products (Prescription and Control of Supply) Regulations (S.I. No. 540 of 2003).

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Rules relate to the situation where a registered pharmaceutical assistant acts on behalf of a registered pharmacist in the temporary absence of the registered pharmacist. They provide for the what constitutes "temporary absence of the registered pharmacist" in that context and lay down rules in relation to the recording of any such periods when a registered pharmaceutical assistant so acts and for the notification of same to members of the public attending the premises. In addition, they provide for the activities which a registered pharmaceutical assistant can carry out on behalf of the registered pharmacist in such a situation, in addition to the registered pharmaceutical assistant's normal activities.

These Rules may be cited as the Pharmaceutical Society of Ireland (Temporary Absence of Pharmacist from Pharmacy) Rules 2018.

These Rules come into operation on xxxxxxx.