



STATUTORY INSTRUMENTS.

S.I. No. [•] of 2016

PHARMACEUTICAL SOCIETY OF IRELAND (REGULATION OF TEMPORARY
ABSENCE COVER BY PHARMACEUTICAL ASSISTANTS) RULES 2016

Draft for Public Consultation

S.I. No. XX of 2016

**PHARMACEUTICAL SOCIETY OF IRELAND (REGULATION OF TEMPORARY
ABSENCE COVER BY PHARMACEUTICAL ASSISTANTS) RULES 2016**

The Council of the Pharmaceutical Society of Ireland, in exercise of the powers conferred on the said Society by section 11 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)) and the Health (Delegation of Ministerial Functions) Order 2014 (S.I. No. 532 of 2014), with the consent of the Minister of State at the Department of Health, hereby makes the following rules:

1. These Rules may be cited as the Pharmaceutical Society of Ireland (Regulation of Temporary Absence Cover by Pharmaceutical Assistants) Rules 2016.

2. These shall come into force on xxxxxxxx

3. In these Rules-

‘Act’ means the Pharmacy Act 2007 (*No. 20 of 2007*) as amended;

‘absence’ means any period during which the pharmacist is not physically present in the retail pharmacy business to exercise his or her professional judgement and responsibility for the personal supervision of the sale and supply of medicinal products;

“duty register” means the ongoing, contemporaneous and retrievable record maintained in accordance with the provisions of regulation 5 (1)(c) of the Regulation of Retail Pharmacy Business Regulations SI 488 of 2008;

‘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;

‘retail pharmacy business’ has the meaning assigned to it in Section 2(1) of the Act;

‘skilled assistance’ means any assistance which consists of or includes or should consist of or include the exercise of the knowledge, ability, judgment and other qualities necessary of a person who is a registered pharmacist or a registered pharmaceutical assistant, including the exercise of that knowledge, ability and judgment and those other qualities by way of the supervision of others;.

‘superintendent pharmacist’ means a registered pharmacist acting in the capacity specified in section 27(b), 28(a) or 29(b) of the Act, who is in personal control of the management and

administration of the sale and supply of medicinal products, either where such control is exercised in respect of a single retail pharmacy business or in respect of a number of such businesses;

‘supervising pharmacist’ means a registered pharmacist acting in the capacity specified in section 27(c), 28(b) or 29(c) of the Act and who is in whole-time charge of carrying on the retail pharmacy business at the premises of the said business;

‘temporary absence’ means any period in the course of which a registered pharmaceutical assistant acts on behalf of the registered pharmacist during the absence of the said registered pharmacist in the conduct of a retail pharmacy business in accordance with the conditions specified in Section 30 of the Act and these Rules;

4. The provisions of these rules shall be without prejudice to the discharge of the role and responsibility of the pharmacy owner, the superintendent pharmacist and of the supervising pharmacist in the premises of the retail pharmacy business where the registered pharmaceutical assistant is acting for any period of temporary absence.
5. The pharmacy owner and the superintendent pharmacist shall ensure that the duty register is completed and clearly indicates the period of time during which the pharmaceutical assistant is acting in the temporary absence of the registered pharmacist, and during which skilled assistance has been provided by the pharmaceutical assistant.
6. A pharmacy owner or superintendent pharmacist shall not operate a retail pharmacy business in the temporary absence of a registered pharmacist unless:
 - a. the period of temporary absence does not exceed 12 hours in any one week, and
 - b. the conditions in Rule 7 and Rule 8 are met.
7. Without prejudice to the provisions of Rule 6, a pharmacy owner or superintendent pharmacist of a registered retail pharmacy business where a registered pharmaceutical assistant acts in the temporary absence of a registered pharmacist, shall not permit the pharmaceutical assistant to act during any period of temporary absence unless the pharmaceutical assistant has provided 12 hours of skilled assistance in the previous month at the same registered retail pharmacy business.
8. A pharmaceutical assistant acting in the temporary absence of a registered pharmacist shall not act in the capacity of the superintendent pharmacist or supervising pharmacist in respect of the registered retail pharmacy business concerned.
9. (1) Without prejudice to the provision of Regulation 5 (1)(h) of the Regulation of Retail Pharmacy Business Regulations 2008, where a Pharmaceutical Assistant is employed or

engaged in a Retail Pharmacy Business to act on behalf of a registered pharmacist in his or her temporary absence, the pharmacy owner and the superintendent pharmacist shall ensure that he or she is satisfied that the Pharmaceutical Assistant has the requisite knowledge, skills, including language skills, and fitness to act on behalf of the registered pharmacist in his or her temporary absence.

(2) For the purposes of paragraph (1) the pharmacy owner and the superintendent pharmacist shall have regard to

- (a) the recent practice experience of the pharmaceutical assistant including but not limited to the skilled assistance provided by the pharmaceutical assistant, and
- (b) the input of the supervising pharmacist of the registered Retail Pharmacy Business concerned in relation to the requirements of Rule 9(1) and subparagraph (a).

10. The duration of temporary absence shall not include absences in circumstances where there is no registered pharmacist permanently employed or engaged on an ongoing basis at the premises of the retail pharmacy business concerned.

11. Pharmacy owners, superintendent pharmacists and supervising pharmacists, in engaging the services of a registered pharmaceutical assistant to act in any period of temporary absence, shall comply with the provisions of these rules.