



STATUTORY INSTRUMENTS.

S.I. No. 74 of 2024

REGULATION OF RETAIL PHARMACY BUSINESSES (AMENDMENT)
REGULATIONS 2024

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I, STEPHEN DONNELLY, in exercise of the powers conferred on me by section 18(1) (as amended by section 32(b) of the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013)) 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)), hereby make the following regulations:

1. (1) These Regulations may be cited as the Regulation of Retail Pharmacy Businesses (Amendment) Regulations 2024.

(2) The Principal Regulations, the Regulation of Retail Pharmacy Businesses (Amendment) Regulations 2016 (S.I. No. 80 of 2016) and these Regulations may be cited together as the Regulation of Retail Pharmacy Businesses Regulations 2008 to 2024.

2. These Regulations come into operation on 1 March 2024.

3. In these Regulations, “Principal Regulations” means the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).

4. The Principal Regulations are amended by inserting after Regulation 9 the following regulation:

“Extension of validity of prescription to more than 6 months after date specified on prescription”

9A. (1) Subject to paragraphs (3) and (4), a person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that a prescription (other than a prescription specifying a period between 6 and 12 months) is not dispensed more than 6 months after the date specified on the prescription unless a registered pharmacist has reviewed the prescription and is satisfied that, having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient including consideration of signs or symptoms indicative of a possible adverse reaction, and having engaged in dialogue with the patient or the patient’s representative—

- (a) the patient has a continuing need or chronic condition that justifies dispensing after the expiry of the period of 6 months,
- (b) the patient’s history with the prescribed medicinal product has not changed,

- (c) the dispensing is in compliance with proper patient care and any additional requirements described in regulatory guidance,
- (d) the dispensing is in the best interests of the patient, and
- (e) appropriate records are retained of the registered pharmacist's decision to dispense under this paragraph as required by Regulation 10E of the Medicinal Products (Prescription and Control of Supply) Regulations 2003,

and, in any event, shall ensure that a prescription is not dispensed more than 12 months after the date specified on the prescription.

(2) Where a prescription is dispensed more than 6 months after the date specified on the prescription pursuant to the exemption provided in paragraph (1), the registered pharmacist who extended the period for dispensing under the prescription shall make reasonable efforts to ensure that the person who prescribed the medicinal product, or another relevant primary healthcare provider, is informed of the decision to extend within the period of 7 days following the decision.

(3) A prescription shall not be dispensed, in accordance with the exemption in paragraph (1), more than 6 months after the date specified on the prescription where—

- (a) the prescriber has indicated that the medicinal product concerned is not to be so dispensed by using the words "do not extend" on the prescription, or
- (b) the medicinal product concerned is a controlled drug specified in Schedule 2, 3 or 4 to the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017).

(4) Notwithstanding paragraph (1), a prescription may be dispensed in the period between 6 and 9 months from the date specified on the prescription, without complying with the provisions of that paragraph, where the date specified is before 1 March 2024."

GIVEN under my Official Seal,
29 February, 2024.

STEPHEN DONNELLY,
Minister for Health.

L.S.

EXPLANATORY NOTE

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

These Regulations amend the Regulation of Retail Pharmacy Businesses Regulations 2008.

The purpose of these Regulations is to allow for the dispensing of prescriptions up to 12 months from the date of the prescription in certain circumstances.

These Regulations may be cited as the Regulation of Retail Pharmacy Businesses (Amendment) Regulations 2024.

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