



STATUTORY INSTRUMENTS.

S.I. No. 73 of 2024

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2024

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2024

I, STEPHEN DONNELLY, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995), hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2024.

(2) The collective citation “the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2024” includes these Regulations.

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

3. In these Regulations, “Principal Regulations” means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

4. Regulation 7 (as amended by Regulation 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023 (S.I. No. 284 of 2023)) of the Principal Regulations is amended—

- (a) in paragraph (2), by substituting “validity of the prescription” for “six months after the date thereon” in both places it occurs,
- (b) by deleting paragraph (2A), and
- (c) in paragraph (5), by substituting for subparagraph (a) the following:

“(a) not be dispensed after the end of—

- (i) the period of 6 months from the date specified on the prescription, or
- (ii) save in the case of a medicinal product which is a controlled drug specified in Schedule 2, 3 or 4 to the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017), a greater period, up to a maximum of 12 months from the date specified on the prescription, where—
 - (I) such period is specified on the prescription, or
 - (II) a registered pharmacist decides that it is appropriate to dispense after the expiry of

the said 6 month period in accordance with Regulation 9A(1) of the Regulation of Retail Pharmacy Business Regulations 2008 (S.I. No. 488 of 2008);”.

5. The Principal Regulations are amended by inserting after Regulation 10D (as amended by Regulation 5 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2023 (S.I. 422 of 2023)) the following regulation:

“Keeping of records in relation to pharmacist decision to extend prescription to more than 6 months after date specified in prescription

10E. A registered pharmacist who makes a decision to extend the validity of a prescription pursuant to Regulation 7(5)(a)(ii)(II) shall, on the making of the first such decision in relation to a prescription, make an entry, in the register kept in accordance with Regulation 10(1), recording the following particulars:

- (a) the date of the decision to extend;
- (b) the name and registration number of the registered pharmacist;
- (c) details of the review undertaken and the decision made by the registered pharmacist pursuant to Regulation 9A(1)(b) of the Regulation of Retail Pharmacy Businesses Regulations 2008; and
- (d) the manner in which the requirement in Regulation 9A(2) of the Regulation of Retail Pharmacy Businesses Regulations 2008 has been complied with.”.

6. Regulation 23 of the Principal Regulations is amended—

- (a) by numbering the existing paragraph as paragraph (1), and
- (b) by inserting after that paragraph the following paragraph:

“(2) Notwithstanding Regulation 7(5)(a), a prescription may be dispensed in the period between 6 and 9 months from the date specified on the prescription, without complying with clause (ii)(II) of that subparagraph, 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 Medicinal Products (Prescription and Control of Supply) Regulations 2003.

The purpose of these Regulations is to provide for the circumstances in which prescriptions may be dispensed more than 6 months after the date specified on the prescription.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2024.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

Tel: 046 942 3100
r-phost: publications@opw.ie

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