STATUTORY INSTRUMENTS.

S.I. No. 138 of 2026

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2026

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I, JENNIFER CARROLL MACNEILL, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 9 of the Health (Miscellaneous Provisions) Act 2024 (No. 23 of 2024)) of the Irish Medicines Board Act 1995 (No. 29 of 1995), hereby make the following regulations:

1. These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2026.

2. The Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2025 and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2026.

3. These Regulations come into operation on 30 June 2026.

4. In these Regulations "Principal Regulations" means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

5. Regulation 7 (as amended by Regulation 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2025 (S.I. No. 502 of 2025)) of the Principal Regulations is amended —

(a) in paragraph (2)—

(i) by substituting for subparagraph (f) the following subparagraph:

"(f) where the dispensing of a prescription has been completed, the person who dispensed it shall forthwith write or print prominently on the prescription—

(i) the word 'dispensed' and the date on which it was dispensed; and

(ii) in the case of a registered pharmacist practising in a retail pharmacy business, the professional registration number of the registered pharmacist by whom such prescription was dispensed;";

(i) by inserting after subparagraph (f) the following subparagraph:

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 14*th April,* 2026.

"(fa) notwithstanding subparagraph (f), where, in the case of a retail pharmacy business—

(i) a prescription is transmitted in electronic form by the national electronic prescription transfer system,

(ii) the dispensing of the prescription has been completed by a registered pharmacist practising in the retail pharmacy business, and

(iii) the electronic copy of the prescription is preserved in accordance with Regulation 10(8)(b)(i),

the requirements of paragraph (2A)(a) shall apply;";

(ii) by substituting for subparagraph (g) the following subparagraph:

"(g) where the prescription is dispensed in part, the person who so dispensed it shall forthwith record on the prescription—

(i) the quantity of each product dispensed by him or her and the date on which he or she dispensed each such quantity;

(ii) the name and address of the person by whom such prescription was dispensed in part; and

(iii) in the case of a registered pharmacist practising in a retail pharmacy business, the professional registration number of the registered pharmacist by whom such prescription was dispensed in part;"; and

(iii) by inserting after subparagraph (g) the following subparagraph:

"(ga) notwithstanding subparagraph (g), where, in the case of a retail pharmacy business—

(i) a prescription is transmitted in electronic form by the national electronic prescription transfer system,

(ii) the prescription is dispensed in part by a registered pharmacist practising in the retail pharmacy business, and

(iii) the electronic copy of the prescription is preserved in accordance with Regulation 10(8)(b)(i),

the requirements of paragraph (2A)(b) shall apply;"; and

(a) by inserting after paragraph (2) the following paragraph:

"(2A) The requirements referred to in paragraph (2)(fa) and (ga), where applicable, are that a registered pharmacist shall, in conjunction with the electronic copy of the prescription preserved in accordance with Regulation 10(8)(b)(i), forthwith enter in a record in electronic form referred to in Regulation 12(1)(c) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) the following particulars, that is to say—

(a) in the case of a prescription referred to in paragraph (2)(fa)—

(i) the date on which the prescription was dispensed by the registered pharmacist; and

(ii) the professional registration number of the registered pharmacist by whom such prescription was dispensed; and

(b) in the case of a prescription referred to in paragraph (2)(ga)—

(i) the quantity of each product dispensed by the registered pharmacist and the date on which he or she dispensed each such quantity; and

(ii) the professional registration number of the registered pharmacist by whom such prescription was dispensed in part.".

1. Regulation 10 (as amended by Regulation 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020)) of the Principal Regulations is amended —

(a) in paragraph (1)—

(i) by substituting "pharmacy owner" for "person keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts, 1875 to 1977"; and

(ii) by substituting "retail pharmacy business" for "shop" in each place where it occurs;

(b) in paragraph (3)—

(i) by substituting "pharmacy owner" for "person keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts 1875 to 1977";

(ii) by substituting "the premises of the" for "such"; and

(iii) by substituting "retail pharmacy business" for "shop";

(c) by substituting for paragraph (5) the following paragraph:

"(5) The requirements of paragraph (1) shall be satisfied in the case of a register referred to in that paragraph kept—

(a) in the form of computerised records provided that—

(i) the information required to be kept by virtue of paragraph (1) is also retained in the form of a print-out for each day on which the retail pharmacy business is open; and

(ii) the print-out referred to in clause (i) shall be dated and certified, on the day to which the print-out relates or within the period of twenty four hours thereafter, by the authorised person by whom the retail pharmacy business is managed;

or

(b) subject to paragraph (7), in the form of an electronic register, which shall be based on a computerised system equivalent to the register.";

(d) by substituting for paragraph (6) the following paragraph:

"(6) References in this regulation to a register shall include, where applicable—

(a) the computerised records and daily print-out referred to in paragraph (5)(a); and

(b) an electronic register referred to in paragraph (5)(b).";

(e) by substituting for paragraph (7) the following paragraph:

"(7) Where a register is an electronic register referred to in paragraph (5)(b), the pharmacy owner shall verify that the computer software in use for the retention of the register ensures that—

(a) the entries in the register are subject to user access controls capable of restricting the functions that may be used;

(b) every alteration to an entry in the register is capable of being traced by identifying the original entry, the alteration to the original entry, the identity of the person who made the alteration and the date of the alteration; and

(c) every entry in the register is capable of being searched, sorted and reproduced by:

(i) the date on which the medicinal product was supplied;

(ii) the name of the medicinal product;

(iii) the strength of the medicinal product, where applicable;

(iv) the name of the person for whom the medicinal product was prescribed or to whom the product was supplied; and

(v) the name of the prescriber, where applicable.";

(f) by substituting for paragraph (8) the following paragraph:

"(8) Notwithstanding paragraph (3)(b), and subject to paragraph (9), in the case of a prescription transmitted by the national electronic prescription transfer system, the person dispensing the prescription shall—

(a) print a copy of the prescription as transmitted and treat the printed copy as an original prescription for the purposes of record-keeping, and the requirements of Regulation 7(2)(f) and (g), where applicable, shall apply in respect of that copy of the prescription as if it were the original prescription; or

(b) (i) preserve an electronic copy of the prescription in a record in electronic form referred to in Regulation 12(1)(c) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) and the requirements referred to in Regulation 7(2)(fa) and (ga), where applicable, shall apply in respect of that electronic copy of the prescription; and

(ii) treat the electronic copy of the prescription referred to in clause (i) as an original prescription for the purposes of record-keeping.";

(g) by inserting after paragraph (8) the following paragraph:

"(9) A pharmacy owner shall ensure that—

(a) a prescription as transmitted by the national electronic prescription transfer system and the copy of such a prescription, made in pursuance of paragraph (8)(a) or (b), are preserved and kept readily available for inspection at the premises of the retail pharmacy business for a period of two years from the relevant date; and

(b) the electronic copy of a prescription referred to in paragraph (8)(b), where applicable, is preserved in such a manner which shall enable the ready identification of—

(i) the prescription used to authorise the dispensing of the medicinal product, or products; and

(ii) the medicinal product, or products, previously dispensed under that prescription."; and

(h) by inserting after paragraph (9) the following paragraph:

"(10) In paragraph (9)(a) the 'relevant date' means:

(a) where the product is supplied in accordance with a repeatable prescription, the date on which the prescription is dispensed for the last time, and

(b) in every other case, the date on which the product is supplied.".

2. Regulation 10B (inserted by Regulation 8 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015)) of the Principal Regulations is amended —

(a) in paragraph (3), by inserting the word "readily" before the word "available";

(b) by substituting for paragraph (4) the following paragraph:

"(4) The requirements of paragraph (1) shall be satisfied in the case of a register referred to in that paragraph kept—

(a) in the form of computerised records if—

(i) there is a print-out, for each day on which the premises of the retail pharmacy business to which the register relates is open for such business, of the particulars recorded in the register pursuant to paragraph (1) during that day; and

(ii) an authorised person certifies, not later than twenty four hours after the print-out is made, the particulars in the print-out are true and correct to the best of his or her knowledge and belief;

or

(b) subject to paragraph (5), in the form of an electronic register, which shall be based on a computerised system equivalent to the register."; and

(c) by inserting after paragraph (4) the following paragraph:

"(5) Where a register is an electronic register referred to in paragraph (4)(b), the pharmacy owner shall verify that the computer software in use for the retention of the register ensures that—

(a) the entries in the register are subject to user access controls capable of restricting the functions that may be used;

(b) every alteration to an entry in the register is capable of being traced by identifying the original entry, the alteration to the original entry, the identity of the person who made the alteration and the date of the alteration; and

(c) every entry in the register is capable of being searched, sorted and reproduced by:

(i) the date on which the medicinal product was supplied;

(ii) the name of the medicinal product;

(iii) the strength of the medicinal product, where applicable; and

(iv) the name of the listed organisation for which the medicinal product was required.".

L.S.

GIVEN under my Official Seal,
9 April, 2026.

JENNIFER CARROLL MACNEILL,
Minister for Health.

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 make provision for certain pharmacy records to be retained electronically and to further specify record-keeping requirements with respect to prescriptions transmitted by the national electronic prescription transfer system.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2026.

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