



STATUTORY INSTRUMENTS.

S.I. No. 98 of 2020

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF
SUPPLY) (AMENDMENT) REGULATIONS 2020

S.I. No. 98 of 2020

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2020

I, SIMON HARRIS, Minister for Health, 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) Regulations 2020.

(2) The Principal Regulations, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), the Regulations of 2007, Part 4 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (S.I. No. 512 of 2008), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009 (S.I. No. 442 of 2009), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011 (S.I. No. 525 of 2011), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014 (S.I. No. 300 of 2014), the Regulations of 2014, the Regulations of 2015, the Regulations (No. 2) of 2015, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018 (S.I. No. 530 of 2018) and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2020.

2. In these Regulations—

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

“Regulations of 2007” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007);

“Regulations of 2014” means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014);

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 10th April, 2020.

“Regulations of 2015” means the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015);

“Regulations (No. 2) of 2015” means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015).

3. Regulation 4(1) (as amended by Regulation 3 of the Regulations (No. 2) of 2015) of the Principal Regulations is amended—

(a) by inserting after the definition of “controlled drug” the following definition:

“‘Covid-19 emergency’ means the situation resulting from the spread in the State of the disease caused by infection with the virus SARS-CoV-2, being a disease specified as an infectious disease in accordance with Regulation 6 of, and the Schedule to, the Infectious Diseases Regulations 1981 (S.I. No. 390 of 1981), or any variant of the disease so specified as an infectious disease in those Regulations;”

(b) by inserting after the definition of “the Minister” the following definition:

“‘national electronic prescription transfer system’ means a system providing for the transfer of prescriptions, in permanent and unalterable form, by electronic means approved, on behalf of the Health Service Executive, by the head of the Primary Care Reimbursement Service (PCRS) and the Chief Information Officer;”, and

(c) by inserting after the definition of “product authorisation” the following definition:

“‘professional registration number’ means—

(a) in the case of a registered medical practitioner, the number attached to the medical practitioner’s registration in accordance with section 43(5) of the Medical Practitioners Act 2007 (No. 25 of 2007),

- (b) in the case of a registered nurse, the number attached to the nurse's registration in accordance with section 46(7) of the Nurses and Midwives Act 2011 (No. 41 of 2011), or
- (c) in the case of a registered dentist, the number assigned by the Dental Council to the dentist's registration in the Register of Dentists in accordance with section 26 of the Dentists Act 1985;”.

4. Regulation 7 (as amended by Regulation 4 of the Regulations of 2014) of the Principal Regulations is amended—

- (a) in paragraph (1), by substituting for subparagraph (a) the following:

“(a) be in—

- (i) ink and be signed by the person issuing it with his or her usual signature and be dated by him or her, or
- (ii) electronic form, transmitted by the national electronic prescription transfer system and clearly indicate the date of issuance and, without prejudice to subparagraph (c)(ii), the professional registration number of the person issuing it, and must be traceable electronically back to him or her;”.

- (b) by inserting after paragraph (2) the following paragraph:

“(2A) Notwithstanding the provisions of paragraph (2), in the circumstances arising from the Covid-19 emergency, the following provisions shall apply to the dispensing of a prescription for the supply of a medicinal product:

- (a) where neither the number of occasions on which, nor the intervals at which, a medicinal product, which is or which contains a substance specified in Part A of the First Schedule and which is not listed in Schedule 2 or 3, or Part 1 of Schedule 4, of the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017), may be supplied are specified in a prescription, the prescription may be dispensed on one additional occasion, where, in the opinion of the person dispensing the prescription, it is—
 - (i) appropriate and necessary for the continued treatment of the person for a further supply to be made, and

- (ii) unreasonable at the time of supply, in the circumstances arising from the Covid-19 emergency, to require the person to obtain a new prescription for that medicinal product;
- (b) where neither the number of occasions on which, nor the intervals at which, a medicinal product, which is or which contains a substance specified in Part B of the First Schedule but which does not contain a substance specified in Part A of the said Schedule, may be supplied are specified in a prescription, the prescription may be dispensed on such number of occasions within the period of nine months after the date thereon as, in the opinion of the person dispensing the prescription, is appropriate and necessary for the continued treatment of the person;
- (c) in the case of a health prescription for a medicinal product, which is or which contains a substance specified in Part A of the First Schedule and which is not listed in Schedule 2 or 3, or Part 1 of Schedule 4, of the Misuse of Drugs Regulations 2017, and which is not ordinarily endorsed to be repeated, where, in the opinion of the person dispensing the prescription, it is appropriate and necessary for the continued treatment of the person for further supplies to be made, the prescription may be dispensed on not more than four occasions;
- (d) where the intervals at which a medicinal product, which is or which contains a substance specified in Part A of the First Schedule, may be supplied, are specified in a prescription but the number of occasions on which it may be supplied are not so specified, the prescription may be dispensed on not more than four occasions;
- (e) where the intervals at which a medicinal product, which is or which contains a substance specified in Part B of the First Schedule but which does not contain a substance specified in Part A of the said Schedule, may be supplied are specified in a prescription, the prescription may be dispensed at those intervals within the period of nine months after the date thereon;
- (f) where the number of occasions on which a medicinal product, which is or which contains a substance specified in either Part A or Part B of the First Schedule, may be supplied is specified in a prescription but the intervals at which it may be supplied are not so specified, the

prescription may be dispensed at such intervals as the person dispensing the prescription considers appropriate having regard to the specified rate of dosage;

- (g) where the number of occasions, as specified on the prescription, on which a medicinal product, which is or which contains a substance specified in either Part A or Part B of the First Schedule, may be supplied has been reached, the prescription may be dispensed on three further occasions where, in the opinion of the person dispensing the prescription, it is appropriate and necessary for the continued treatment of the person for further supplies to be made;
 - (h) where the dispensing of a prescription has been completed before the commencement of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020), and the prescription has been endorsed in accordance with paragraph (2)(f), additional supplies may be made against such prescription, subject to the provisions of subparagraphs (a) to (g);
 - (i) where the original prescription is not available, a medicinal product may nonetheless be supplied in accordance with this paragraph and paragraph (2)(f) and (g) shall not apply, provided the person dispensing the prescription makes a record of the reasons for the making of the supply.”, and
- (c) in paragraph (5)—
- (i) in subparagraph (a), by substituting “nine” for “six”, and
 - (ii) by substituting for subparagraph (b) the following:
 - “(b) except in the case of—
 - (i) a health prescription that is a repeatable prescription upon which a second or subsequent supply of a medicinal product is being made,
 - (ii) a prescription transmitted in electronic form via the national electronic prescription transfer system, or
 - (iii) a prescription dispensed pursuant to paragraph (2A),
 be an original as issued by the registered medical practitioner, registered dentist or registered nurse;”.

5. Regulation 8 (as amended by Regulation 6 of the Regulations of 2007) of the Principal Regulations is amended—

- (a) in paragraph (2)(b), by substituting “10 days” for “5 days”, and
- (b) by inserting after paragraph (3) the following paragraphs:

“(4) Notwithstanding the provisions of paragraphs (1)(d) and (2)(c), in the circumstances arising from the Covid-19 emergency, an authorised person who supplies a controlled drug specified in Schedule 2, 3 or 4 to the Misuse of Drugs Regulations 2017 otherwise than in accordance with a prescription is not guilty of an offence where, in the opinion of the authorised person, it is—

- (a) unreasonable at the time of supply, in the circumstances arising from the Covid-19 emergency, for the person to obtain a new prescription for that medicinal product, and
- (b) safe, appropriate and necessary for the continued treatment of the person for an emergency supply to be made,

and no greater quantity of the product than will provide 5 days’ treatment is supplied.

(5) Notwithstanding the provisions of paragraphs (1)(d), (2)(c) and (4), in the circumstances arising from the Covid-19 emergency, the conditions specified in paragraph (1)(d) and (2)(c) shall not apply where the product consists of or contains midazolam, clobazam or clonazepam (but no other substance specified in the Fourth Schedule or in Schedule 1, 2, 3 or 4 to the Misuse of Drugs Regulations 2017 or any amendment thereof) and is supplied for the treatment of epilepsy.”.

6. Regulation 10 (as amended by Regulation 5 of the Regulations of 2015) of the Principal Regulations is amended by inserting after paragraph (6) the following paragraphs:

“(7) Notwithstanding paragraph (3)(b), in the case of a prescription transmitted by the national electronic prescription transfer system, the person dispensing the prescription shall—

- (a) print the prescription as transmitted and treat it as an original prescription for the purposes of record-keeping, and
- (b) preserve and keep available for inspection for a period of two years from the relevant date that printed copy and the electronic version of the prescription.

(8) Notwithstanding paragraph (3)(b), in the case of a prescription dispensed in accordance with Regulation 7(2A) where the original prescription is not available, the person dispensing the prescription shall preserve and keep available for inspection for a period of two years from the date of supply the record referred to in Regulation 7(2A)(i).”.



GIVEN under my Official Seal,
2 April, 2020.

SIMON HARRIS,
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 introduce temporary measures to address the Covid-19 emergency.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2,
D02 DR67.

Teil: 076 110 6834
r-post: publications@opw.ie

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2,
D02 DR67.

Tel: 076 110 6834
E-mail: publications@opw.ie

€ 3.00

