STATUTORY INSTRUMENTS.

S.I. No. 72 of 2024

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2024

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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) Regulations 2024.

(2) The Principal Regulations, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 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 Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014 (S.I. No. 504 of 2014), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018 (S.I. No. 530 of 2018), Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2020 (S.I. No. 177 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2020 (S.I. No. 204 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2020 (S.I. No. 241 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020 (S.I. No. 401 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2020 (S.I. No. 614 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (S.I. No. 698 of 2020), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2021 (S.I. No. 2 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021 (S.I. No. 8 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2021 (S.I. No. 43 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021 (S.I. No. 81 of 2021), the Medicinal Products (Prescription and Control of Supply)

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st March,* 2024.

(Amendment) (No. 5) Regulations 2021 (S.I. No. 130 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2021 (S.I. No. 155 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021 (S.I. No. 245 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 8) Regulations 2021 (S.I. No. 411 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 9) Regulations 2021 (S.I. No. 492 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021 (S.I. No. 511 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 11) Regulations 2021 (S.I. No. 558 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 12) Regulations 2021 (S.I. No. 578 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 13) Regulations 2021 (S.I. No. 605 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 14) Regulations 2021 (S.I. No. 692 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021 (S.I. No. 718 of 2021), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2022 (S.I. No. 32 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2022 (S.I. No. 57 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2022 (S.I. No. 84 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2022 (S.I. No. 402 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2022) (S.I. No. 467 of 2022), the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2023 (S.I. No. 11 of 2023), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2023 (S.I. No. 105 of 2023), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2023 (S.I. No. 238 of 2023), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023 (S.I. No. 284 of 2023), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2023 (S.I. No. 422 of 2023), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2023 (S.I. No. 451 of 2023), the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2023 (S.I. No. 584 of 2023) and these Regulations may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2024.

2. The 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);

"Regulations of 2023" means the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023) (S.I. No. 284 of 2023).

4. Regulation 8 (as amended by Regulation 7 of the Regulations of 2023) of the Principal Regulations is amended—

(a) in paragraph (2)(b), by substituting "5 days' treatment or the nearest equivalent minimum dosage pack unit size" for "10 days' treatment",

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

"(4) Notwithstanding the provisions of paragraphs (1)(d) and (2)(c), 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—

(a) there is an immediate need for the medicinal product containing the controlled drug to be supplied,

(b) it is safe, appropriate and necessary for the continued treatment of the person for an emergency supply to be made,

(c) it is not possible to obtain a prescription without undue delay,

(d) treatment with the product has, on a previous occasion, been prescribed for the person,

(e) no greater quantity of the product than will provide 5 days' treatment, or the nearest equivalent minimum dosage pack unit size, is being supplied, and

(f) where the medicinal product is supplied in accordance with paragraph (2), the person has not already been supplied with the medicinal product in accordance with the exemption provided in that paragraph since such previous prescription.", and

(c) in paragraph (5), by deleting ", in the circumstances arising from the Covid-19 emergency".

L.S.

GIVEN under my Official Seal,
29 February, 2024.

STEPHEN DONNELLY,
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 amend the provisions providing for exemptions for emergency supply.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2024.

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