



STATUTORY INSTRUMENTS.

S.I. No. 504 of 2025

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET)
(AMENDMENT) REGULATIONS 2025

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I, JENNIFER CARROLL MACNEILL, 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), and including for the purpose of giving further effect to Directive 2001/83/EC of the European Parliament and of the Council of 06 November 2001 on the Community Code relating to medicinal products for human use¹ (as amended by Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC)², hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2025.

(2) The Principal Regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 3 of 2009), the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009 (S.I. No. 553 of 2009), the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2010 (No. 287 of 2010), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2011 (S.I. No. 722 of 2011), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013 (S.I. No. 162 of 2013), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014 (S.I. No. 151 of 2014), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2018 (S.I. No. 529 of 2018), Regulation 6 of Medicinal Products (Safety Features On Packaging) Regulations 2019 (S.I. No. 36 of 2019), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2019 (S.I. No. 218 of 2019), the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2022 (S.I. No. 416 of 2022) and these Regulations may be cited together as “the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2025”.

2. In these Regulations “Principal Regulations” means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

¹ Official Journal No. L 311, 28.11.2001, p. 67.

² OJ No. L 157, 20.6.2023, p. 1.

3. Regulation 3(1) of the Principal Regulations (as amended by Regulation 4 of the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2022 (S.I. No. 416 of 2022)) is amended by substituting for the definition of “practitioner” the following:

“‘practitioner’ means a registered dentist, a registered medical practitioner, a registered nurse prescriber, a registered mid-wife prescriber or a pharmacist””.



GIVEN under my Official Seal,
23 October, 2025.

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 definition of “practitioner” in the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

The purpose of these Regulations is to support the implementation of the Common Conditions Service by adding “pharmacist” to the definition of “practitioner”.

These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2025.

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