



STATUTORY INSTRUMENTS.

S.I. No. 555 of 2022

EUROPEAN COMMUNITIES (CONTROL OF DRUG PRECURSORS)
(AMENDMENT) REGULATIONS 2022

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I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving full effect to Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015¹ and Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015², hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Control of Drug Precursors) (Amendment) Regulations 2022.
(2) The Principal Regulations and these Regulations may be cited together as the European Communities (Control of Drug Precursors) Regulations 2009 and 2022.
2. In these Regulations “Principal Regulations” means the European Communities (Control of Drug Precursors) Regulations 2009 (S.I. No. 558 of 2009).
3. Regulation 2(1) of the Principal Regulations is amended—
 - (a) in the definition of “authorised officer”, by substituting “Regulation 24” for “Regulation 23”,
 - (b) by substituting for the definition of “Board” the following definition:

“Authority” means the Health Products Regulatory Authority”,
 - (c) in the definition of “EC Regulations”, by substituting “Regulation 2015/1011 and Regulation 2015/1013” for “and Regulation 1277/2005”,
 - (d) in the definition of “Regulation 273/2004”, by inserting “as amended from time to time” after “drug precursors”,
 - (e) in the definition of “Regulation 111/2005”, by inserting “as amended from time to time” after “drug precursors”,
 - (f) by substituting for the definition of “Regulation 1277/2005” the following definitions:

“Regulation 2015/1011” means Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015¹;

¹ OJ No. L 162, 27.6.2015, p. 12.

² OJ No. L 162, 27.6.2015, p. 33.

‘Regulation 2015/1013’ means Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015²;”,

- (g) in the definition of “special licensed operators”, by substituting “Article 3(12) of Regulation 2015/1011” for “Article 12(2) of Regulation 1277/2005”, and
- (h) in the definition of “special registered operators”, by substituting “Article 3(12) of Regulation 2015/1011” for “Article 12(2) of Regulation 1277/2005”.

4. Regulation 3 of the Principal Regulations is amended—

- (a) in paragraph (1)—
 - (i) in subparagraph (b), by substituting “Regulation 111/2005,” for “Regulation 111/2005, and”, and
 - (ii) by substituting for subparagraph (c) the following subparagraphs:
 - “(c) Articles 8 and 9 of Regulation 2015/1011, and
 - “(d) Article 11 of Regulation 2015/1013.”,
- (b) in paragraph (2)—
 - (i) by substituting “Authority” for “Board”,
 - (ii) in subparagraph (b), by substituting “Regulation 111/2005,” for “Regulation 111/2005, and”, and
 - (iii) by substituting for subparagraph (c) the following subparagraphs:
 - “(c) Articles 3, 9, 11 and 12 of Regulation 2015/1011, and
 - “(d) Articles 3, 4, 5, 6, 7, 10 and 11 of Regulation 2015/1013.”, and
- (c) in paragraph (3), by substituting for subparagraph (c) the following:

“(c) Articles 8 and 9 of Regulation 2015/1011.”.

5. Regulation 5 of the Principal Regulations is amended—

- (a) in paragraph (1), by substituting “Article 3 of Regulation 2015/1011” for “Article 5 of Regulation 1277/2005”,
- (b) in paragraph (2), by substituting “Article 3 of Regulation 2015/1013” for “Article 7 of Regulation 1277/2005”,
- (c) in paragraph (3), by substituting “Article 3 of Regulation 2015/1013” for “Article 7 of Regulation 1277/2005” in both places it occurs,
- (d) in paragraph (7), by substituting “Article 3(9) of Regulation 2015/1011” for “Article 10(2) of Regulation 1277/2005”,

- (e) in paragraph (8), by substituting “Article 6 of Regulation 2015/1013” for “Article 10(3) of Regulation 1277/2005”, and
 - (f) in paragraph (9), by substituting “Article 7(1) of Regulation 2015/1013” for “Article 10(4) of Regulation 1277/2005”.
6. Regulation 7 of the Principal Regulations is amended—
- (a) in paragraph (1), by substituting “Article 3 of Regulation 2015/1011 shall pay such fee as may be levied by the Authority in accordance with Article 3(6c) of Regulation 273/2004” for “Article 5 of Regulation 1277/2005 shall pay a fee of €63.50”, and
 - (b) in paragraph (2), by substituting “such fee as may be levied by the Authority in accordance with Article 3(6c) of Regulation 273/2004” for “a fee of €63.50”.
7. Regulation 8(5) of the Principal Regulations is amended by substituting “Article 7 of Regulation 2015/1011” for “Article 15 of Regulation 1277/2005”.
8. Regulation 11 of the Principal Regulations is amended—
- (a) in paragraph (2), by substituting “Article 9(1) of Regulation 2015/1011 within the timeframe specified in Article 10 of Regulation 2015/1013” for “Article 17 of Regulation 1277/2005 within the timeframe specified in Article 19 of Regulation 1277/2005”, and
 - (b) in paragraph (3), by substituting “Article 10 of Regulation 2015/1013” for “Article 19 of Regulation 1277/2005”.
9. Regulation 12(2) of the Principal Regulations is amended—
- (a) by substituting “Article 3(1) of Regulation 2015/1011” for “Article 3 of Regulation 1277/2005”, and
 - (b) by substituting “the second subparagraph of that provision” for “Article 4 of Regulation 1277/2005”.
10. Regulation 14 of the Principal Regulations is amended—
- (a) in paragraph (1), by substituting “Article 3 of Regulation 2015/1011” for “Article 5 of Regulation 1277/2005”,
 - (b) in paragraph (3), by substituting “Article 3(9) of Regulation 2015/1011” for “Article 10(2) of Regulation 1277/2005”,
 - (c) in paragraph (4), by substituting “Article 6 of Regulation 2015/1013” for “Article 10(3) of Regulation 1277/2005”, and

- (d) in paragraph (5), by substituting “Article 7 of Regulation 2015/1013” for “Article 10(4) of Regulation 1277/2005”.

- 11. Regulation 16 of the Principal Regulations is amended by substituting “Article 8 of Regulation 2015/1011” for “Article 16 of Regulation 1277/2005” in both places it occurs.

- 12. Regulation 17 of the Principal Regulations is amended—
 - (a) in paragraph (2), by substituting “Article 9(1) of Regulation 2015/1011 within the timeframe specified in Article 10 of Regulation 2015/1013” for “Article 18 of Regulation 1277/2005 within the timeframe specified in Article 19 of Regulation 1277/2005”, and
 - (b) in paragraph (3), by substituting “Article 10 of Regulation 2015/1013” for “Article 19 of Regulation 1277/2005”.

- 13. Regulation 18 of the Principal Regulations is amended—
 - (a) in paragraph (1), by substituting “Article 10 of Regulation 2015/1011” for “Article 22 of Regulation 1277/2005”, and
 - (b) in paragraph (2), by substituting “Article 11(2) and (4) of Regulation 2015/1013” for “Article 23 of Regulation 1277/2005” in each place it occurs.

- 14. Regulation 19 of the Principal Regulations is amended—
 - (a) by substituting for paragraph (1) the following:

“19. (1) An operator having a valid operative export authorisation by simplified procedure in accordance with Article 19 of Regulation 111/2005 and Article 12 of Regulation 2015/1011 shall be guilty of an offence if the operator fails to comply with the requirements of Article 11(8), (9) and (10) of Regulation 2015/1013 when establishing such authorisation.”, and
 - (b) in paragraph (2), by substituting “Article 12(2) of Regulation 2015/1011” for “Article 26 of Regulation 1277/2005”.

- 15. Regulation 20 of the Principal Regulations is amended by substituting for paragraph (2) the following:

“(2) An operator importing or attempting or seeking to import, scheduled substances shall be guilty of an offence if the operator fails to comply with Article 22 of Regulation 111/2005 or Article 11(3) or (4) of Regulation 2015/1013.”.

16. Regulation 21 of the Principal Regulations is amended—

- (a) in paragraph (1), by substituting “Article 3 of Regulation 2015/1011, shall pay such fee as may be levied by the Authority in accordance with Article 3(6c) of Regulation 273/2004” for “Article 5 of Regulation 1277/2005, shall pay a fee of €63.50”,
- (b) in paragraph (2), by substituting “such fee as may be levied by the Authority in accordance with Article 3(6c) of Regulation 273/2004” for “a fee of €63.50”, and
- (c) in paragraph (3), by substituting “such fee as may be levied by the Authority in accordance with Article 3(6c) of Regulation 273/2004” for “a fee of €63.50”.

17. Regulation 22(1) of the Principal Regulation is amended by substituting “section 50 of the Customs Act 2015” for “the Customs Consolidation Act 1876, the Customs Act 1956 and the Customs and Excise (Miscellaneous Provisions) Act 1988”.

18. The Principal Regulations are amended by substituting for Part 4 the following:

“PART 4

REGULATION 2015/1011

23. (1) An operator who fails to take adequate security measures in accordance with Article 3(2)(a) of Regulation 2015/1011, shall be guilty of an offence.

(2) An operator who attempts to transfer a licence issued in accordance with the EC Regulations, in breach of Article 3(8) of Regulation 2015/1011, shall be guilty of an offence.”.

19. Regulation 36(1) of the Principal Regulations is amended by substituting “Article 3(9) of Regulation 2015/1011” for “Article 10(2) of Regulation 1277/2005”.



GIVEN under my Official Seal,
28 October, 2022.

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 European Communities (Control of Drug Precursors) Regulations 2009 to take account of the replacement of Commission Regulation (EC) No. 1277/2005 of 26 July 2005 with Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015 and Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015.

These Regulations may be cited as the European Communities (Control of Drug Precursors) (Amendment) Regulations 2022.

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