



STATUTORY INSTRUMENTS.

S.I. No. 3 of 2024



EUROPEAN UNION (CLINICAL TRIALS ON MEDICINAL PRODUCTS
FOR HUMAN USE) (AMENDMENT) REGULATIONS 2024

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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 further effect to Regulation (EC) No. 536/2014 of 16 April 2014¹, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2024.

(2) The Principal Regulations, the European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) (Amendment) Regulations 2022 (S.I. No. 418 of 2022) and these Regulations may be cited together as the European Union (Clinical Trials on Medicinal Products for Human Use) Regulations 2022 to 2024.

2. In these Regulations—

“Principal Regulations” means the European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (S.I. No. 99 of 2022);

“Regulations of 2022” means the European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) (Amendment) Regulations 2022 (S.I. No. 727 of 2022).

3. The Principal Regulations are amended by substituting for Regulation 61A (inserted by Regulation 2 of the Regulations of 2022) the following:

“61A. A notice of amendment under Regulation 21(3) of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to which Regulation 61(a) applies shall be made to the National Office and, in the case of commercial trials, a fee of €400 shall apply in connection with each such notification.”.

4. The Regulations of 2022 are revoked.



GIVEN under my Official Seal,
8 January, 2024.

STEPHEN DONNELLY,
Minister for Health.

¹ OJ No. L 158, 27.5.2014, p. 1.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations amend the European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 to update the fees payable to the National Office in respect of applications coming under the remaining transitional provisions that apply in respect of the repeal of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004.

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