STATUTORY INSTRUMENTS.

S.I. No. 727 of 2022

EUROPEAN UNION (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE) (PRINCIPAL) (AMENDMENT) REGULATIONS 2022

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EUROPEAN UNION (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE) (PRINCIPAL) (AMENDMENT) REGULATIONS 2022

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 2014[1], hereby make the following regulations:

1. These Regulations may be cited as the European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) (Amendment) Regulations 2022.

2. The European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (S.I. No. 99 of 2022) are amended by inserting after Regulation 61 the following regulation:

"61A. An application to which Regulation 61(a) applies, and which relates to the whole State, shall be made to the National Office and the following fees shall be payable by the applicant to the National office:

(a) in the case of an application under Regulation 12 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004—
(i) €1,500 for commercial trials, or
(ii) €150 for non-commercial trials,

in connection with each such application, with no fee for each additional trial site to which the application relates; and

(b) in the case of a notification of amendment under Regulations 21(3) of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004—
(i) €400 for commercial trials, or
(ii) €50 for non-commercial trials,

in connection with each such notification.".

L.S.

GIVEN under my Official Seal,
23 December, 2022.

STEPHEN DONNELLY,
Minister for Health.

[1] OJ No. 158, 27.5.2014, p. 1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 3rd *January,* 2023.

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 provide for fees payable to the National Office in respect of applications coming under the 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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