STATUTORY INSTRUMENTS.

S.I. No. 418 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

The Minister for Health, in exercise of the powers conferred on him by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Regulation (EU) No. 2022/641 of 12 April 2022[1], hereby makes 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. These Regulations shall be deemed to have come into operation on 02 March 2022.

3. 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).

4. Regulation 3(1) of the Principal Regulations is amended –
   (a) by substituting for the definition of "Clinical Trials Regulation" the following:
   "'Clinical Trials Regulation' means Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014[1] on clinical trials on medicinal products for human use (as amended);",
   (b) by substituting for the definition of "Directive" the following:
   "'Directive' means Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001[4] (as amended);", and
   (c) by substituting for the definition of "Directive 2001/83/EC" the following:
   "'Directive 2001/83/EC[6] means Directive 2001/83/EC of the European Parliament and of the Council (as amended);".

5. The Principal Regulations are amended by substituting for Regulation 28 the following:
"28. (1) Subject to paragraph (2), in accordance with Article 61(1) of the Clinical Trials Regulation, the manufacturing and importation of investigational medicinal products shall be subject to the holding of a manufacturer's authorisation.

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[1] OJ No. L. 118, 20.04.2022, p.1.
[1] OJ No. L. 158, 27.5.2014, p. 1.
[4] O.J. No. L 121, 1.5.2001, p. 34.
[6] O.J. No. L 311, 28.11.2001, p. 67.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 23*rd August,* 2022.

(2) Until 31 December 2024, the import of investigational medicinal products from parts of the United Kingdom other than Northern Ireland shall not be subject to the holding of a manufacturer's authorisation provided that all of the following conditions are fulfilled –

(a) the investigational medicinal products have undergone certification of batch release either in the Union or in parts of the United Kingdom other than Northern Ireland to verify compliance with the requirements set out in Article 63(1) of the Clinical Trials Regulation, and

(b) the investigational medicinal products are only made available to subjects in the State."

L.S.

GIVEN under the Official Seal of the Minister for Health,
18 August, 2022.

MUIRIS O'CONNOR,
A person authorised under section 15 of the Ministers and Secretaries Act 1924 to authenticate the seal of the Minister for Health.

EXPLANATORY NOTE

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

The main purpose of these Regulations is to implement Article 1 of Regulation (EU) No. 2022/641 of 12 April 2022, which amends Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products.

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Teil: 046 942 3100
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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
MOUNTSHANNON ROAD,
KILMAINHAM, DUBLIN 8,
D08 XAO6

Tel: 046 942 3100
E-mail: publications@opw.ie

ISBN 978-1-3993-1822-8

€ 3.00

(DH-440) 75. 8/22. Propylon.