STATUTORY INSTRUMENTS.

S.I. No. 417 of 2022

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

S.I. No. 417 of 2022

EUROPEAN COMMUNITIES (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE) (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 Directive (EU) 2022/642[1] of the European Parliament and of the Council of 12 April 2022, hereby makes the following regulations:

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

2. These Regulations shall be deemed to have come into operation on 1 January 2022.

3. In these Regulations "Principal Regulations" means the European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations 2004 (S.I. No. 190 of 2004).

4. Regulation 4(1) is amended -

(a) by substituting for the definition of "Directive" the following:

"'Directive' means Directive 2001/20/EC[1] of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (as amended);",

(b) by substituting for the definition of "Directive 2001/83/EC" the following:
"'Directive 2001/83/EC' means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use[3] (as amended);",

(c) by substituting for the definition of "export" the following:
"'export' means export to a third country, other than Northern Ireland, from the State, whether by land, sea or air;", and

(d) by substituting for the definition of "import" the following:
"'import' means import to the State from a third country, other than Northern Ireland, whether by land, sea or air;".

[1] OJ No. L. 118, 20.4.2022, p.4.
[1] OJ No. L. 121, 01.05.2001, p.34.
[3] OJ 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.

5. Regulation 11 of the Principal Regulations is hereby amended –

(a) by substituting for subparagraph 2(c) the following:

"(c) in the case of an investigational medicinal product –

(i) imported from a third country, the product has been imported by a person holding a manufacturing authorisation relating to the importation of that product, or

(ii) imported from parts of the United Kingdom other than Northern Ireland, until 31 December 2024, the Board may allow product to be imported in the absence of a manufacturing authorisation relating to the importation of that product following receipt of a request from the sponsor provided that all of the following conditions are fulfilled –

(I) the investigational medicinal products imported into the State have undergone certification of batch release either in the Union, as provided for in Article 13, paragraph 3, point (a) of the Directive or in parts of the United Kingdom other than Northern Ireland in compliance with the requirements set out in Article 13, paragraph 3, point (b) of the Directive, and

(II) the investigational medicinal products are only made available to subjects in the State; and"

(b) by substituting for subparagraph 2(d) the following:

"(d) the production batch of investigational medicinal product of which the product is a part has been checked and certified by a qualified person pursuant to Regulation 40 who operates in –

(i) an EEA State,

(ii) Northern Ireland, or

(iii) until 31 December 2024, parts of the United Kingdom other than Northern Ireland and the investigational medicinal product is only made available to subjects in the State."

6. The Principal Regulations are amended by inserting after Part 9 the following Part:

"PART 10

DEROGATIONS

53. (1) By 20 May 2022, the Board shall establish, notify to the Commission and publish on its website a list of medicinal products to which it has applied or intends to apply the derogations as set out in Regulations 11(2)(c) and 11(2)(d) of these Regulations.

(2) The Board shall ensure that the list referred to in paragraph (1) is updated at least on a six-monthly basis.

(3) Any sponsor who intends to avail of the derogations set out in Regulations 11(2)(c) and 11(2)(d) of these Regulations for an investigational medicinal product shall notify the Board and ensure that the relevant investigational medicinal product is included on the list referred to in paragraph (1) before the relevant investigational medicinal product is supplied for use in the clinical trial."

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 Articles 1 and 2(11) of Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022, which amend Directive 2001/20/EC and Directive 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

Teil: 046 942 3100
r-phost: publications@opw.ie

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 978-1-3993-1821-1

€ 3.00

(DH-439) 75. 8/22. Propylon.