



AN BILLE UM RIALÚ TRIALACHA AGUS DRUGAÍ
CLINICIÚLA, 1990
CONTROL OF CLINICAL TRIALS AND DRUGS BILL, 1990

EXPLANATORY AND FINANCIAL MEMORANDUM

The Control of Clinical Trials and Drugs Bill, 1990, seeks to amend the Control of Clinical Trials Act, 1987, (hereinafter referred to as the Principal Act), to provide certain legal immunities for the National Drugs Advisory Board in the exercise of its functions and to provide for matters connected therewith.

In particular,

- section 2* seeks to amend section 6 of the Principal Act to further clarify the definition of “conduct a clinical trial” by amending the exemption thereto as provided in section 6 (2) (a) (ii) of the Principal Act,
- section 3* seeks to amend section 10 of the Principal Act by requiring that a person shall neither arrange for the conducting nor conduct a clinical trial unless he establishes to the satisfaction of the Minister that adequate security is available and thereby removing from Ethics Committees the responsibility to be satisfied as to the adequacy of such security as required by section 10 of the Principal Act.
- section 4* seeks to amend section 13 of the Principal Act to include provision for offences and defences by persons purporting to act on behalf of a body corporate or on behalf of an unincorporated body of persons,
- section 5* seeks to provide certain legal immunities for the Minister, the National Drugs Advisory Board and Ethics Committees in relation to their functions under the Principal Act and under the provisions of the Bill and for the National Advisory Board in relation to its functions under Article 4 of the National Drugs Advisory Board (Establishment) Order, 1966 and for committees established under Article 18 of the same order.

The Bill has no staff or financial implications.

*An Roinn Sláinte,
Meitheamh, 1990.*



AN BILLE UM RIALÚ TRIALACHA AGUS DRUGAÍ CLINIÚLA, 1990
CONTROL OF CLINICAL TRIALS AND DRUGS BILL, 1990

BILLE

BILL

EXPLANATORY AND FINANCIAL MEMORANDUM
(mar a thionscnaíodh sa Seánad) (as introduced in the Seanad)

Acht de leas agus do bheith a bhaineann le h-athrú agus do leasú ar an Bille um Rialú Trialacha agus Drugaí Cliniúla, 1987 (hereinafter referred to as the Principal Act) to provide certain legal immunities for the National Drugs Advisory Board in the exercise of its functions and to provide for the amendment of certain provisions of the said Bill, 1987.

section 2 seeks to amend section 6 of the Principal Act to further clarify the definition of "conduct a clinical trial" by amending the exemption thereto as provided in section 6 (2) (a) (ii) of the Principal Act.

section 3 seeks to amend section 10 of the Principal Act by requiring that a person shall neither arrange for the conducting nor conduct a clinical trial unless he establishes to the satisfaction of the Minister that adequate security is available and thereby removing from Ethics Committees the responsibility to be satisfied as to the adequacy of such security as required by section 10 of the Principal Act.

An Seanadóir Seán Ó Fúillín a thionscnaíodh sa Seánad ar 14 Meitheamh, 1990.

section 4 seeks to amend section 13 of the Principal Act to include provision for offences and offences by persons purporting to act on behalf of a body corporate or on behalf of an unincorporated body of persons.

section 5 seeks to provide certain legal immunities for the Minister, the National Drugs Advisory Board and Ethics Committees in relation to their functions under the Principal Act and under the provisions of the Bill and for the National Drugs Advisory Board in relation to its functions under Article 4 of the National Drugs Advisory Board (Establishment) Order, 1986 and for committees established under Article 18 of the same order.

BAILE ÁTHA CLIATH:
ARNA FHOILSIÚ AG OIFIG AN SOLÁTHAIR

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