
STATUTORY INSTRUMENTS

1995 No. 2809

MEDICINES

**The Medicines (Exemption from Licences
and Certificates) (Clinical Trials) Order 1995**

Made - - - - *27th October 1995*

Coming into force - - *8th December 1995*

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively and the Department of Health and Social Services for Northern Ireland, acting jointly in exercise of the powers conferred upon them by sections 35(8)(a) and 129(4) of the Medicines Act 1968⁽¹⁾ or, as the case may be, those conferred by those provisions and now vested in them⁽²⁾ and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by this Order⁽³⁾, hereby make the following Order:

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Exemption from Licences and Certificates) (Clinical Trials) Order 1995 and shall come into force on 8th December 1995 immediately after the Medicines (Exemption from Licences) (Clinical Trials) Order 1995⁽⁴⁾ comes into force.

(2) In this Order—

“the Act” means the Medicines Act 1968;

“medicinal product” includes any substance or article for human use specified in an order made under section 104 or 105(1)(b) of the Act (application of Act to certain articles and substances and to certain other substances which are not medicinal products) which is for the time being in force and which directs that sections 31 and 35(8) and (9) of the Act shall have effect in relation to that substance or article⁽⁵⁾.

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- (1) 1968 c. 67. The expressions “the Health Ministers” and “the appropriate Ministers” are defined in section 1 of that Act as amended by S.I. 1969/388, Schedule 1.
- (2) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); in the case of the Department of Health and Social Services for Northern Ireland by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).
- (3) See section 129(6) of the Medicines Act 1968.
- (4) S.I. 1995/2808.
- (5) See the Medicines (Surgical Materials) Order 1971 (S.I. 1971/1267), the Medicines (Dental Filling Substances) Order 1975 (S.I. 1975/533) and the Medicines (Specified Articles and Substances) Order 1976 (1976/968), each amended by the Medical Devices (Consequential Amendments – Medicines) Regulations 1994 (S.I. 1994/3119).

Exemption from licences and certificates in respect of clinical trials

2.—(1) Subject to paragraph (2) of this article, the restrictions imposed by section 31(2) of the Act (which restricts dealings with medicinal products for the purposes of a clinical trial) shall not apply to anything done which consists of selling or supplying, or procuring the sale, supply, manufacture or assembly of, a medicinal product for the purposes of a clinical trial.

(2) the exemption conferred by paragraph (1) of this article is subject to the conditions specified in article 4 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995 and to the limitations specified in article 5 of that Order.

Revocation

3. The Medicines (Exemption from Licences) (Clinical Trials) Order 1981(6) is hereby revoked.

24th October 1995

Tom Sackville
Secretary of State for Health

27th October 1995

William Hague
Secretary of State for Wales

25th October 1995

James Douglas-Hamilton
Minister of State, The Scottish Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland
on

L.S.

25th October 1995.

F. A. Elliott
Permanent Secretary

(6) [S.I. 1981/164](#), amended by [S.I. 1995/2808](#).

EXPLANATORY NOTE

(This note is not part of the Order)

This Order comes into force immediately after the coming into force of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995 (“the Exemption Order”) and together these Orders effect the revocation and replacement of the Medicines (Exemption from Licences) (Clinical Trials) Order 1981 (“the 1981 Order”). The 1981 Order granted, in respect of medicinal products for use in clinical trials, exemption from restrictions imposed by Part II of the Medicines Act 1968 (“the Act”) on certain dealings in medicinal products without product licences or clinical trial certificates. The 1981 Order specified conditions subject to which the exemption applied, and provided for the termination of the exemption in specified circumstances.

Article 2 of this Order exempts certain dealings in medicinal products, for the purposes of a clinical trial, from the restrictions imposed by section 31(2) of the Act. The exemption is subject to the conditions and other provisions set out in articles 4 and 5 of the Exemption Order.

Article 3 revokes the 1981 Order (which was amended by the Exemption Order).