STATUTORY INSTRUMENTS

1981 No. 164

MEDICINES

The Medicines (Exemption from Licences) (Clinical Trials) Order 1981

Made - - - -	11*th February* 1981
Laid before Parliament	18*th February* 1981
Coming into Operation	11*th March* 1981

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred by sections 15(1) and (2) and 35(8)(*a*) and (9) of the Medicines Act 1968**(a)** and now vested in them**(b)** 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 the following Order, hereby make the following Order:—

Citation and commencement

1. This Order may be cited as the Medicines (Exemption from Licences) (Clinical Trials) Order 1981 and shall come into operation on 11th March 1981.

Interpretation

2.—(1) In this Order—

(*a*) "the Act" means the Medicines Act 1968;

"approved name" in relation to a constituent is either the name of the substance or article which appears in the current edition of the list prepared by the appropriate body in accordance with section 100 of the Act and published by the Ministers on the recommendation of the Medicines Commission or the international non-proprietary name recommended by the World Health Organisation;

"medicinal product" includes any substance or article for human use specified in an order made under section 104 or section 105(1)(*b*) of the Act which is for the time being in force and which directs that sections 31 and 35(8) and (9) shall have effect in relation to that substance or article**(c)**;

(a) 1968 c. 67.

(b) 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) and 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).

(c) 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 (S.I. 1976/968).

"monograph" means a monograph in the current edition, of the European Pharmacopoeia, of any compendium published by the Ministers under section 99 of the Act, of the British Pharmacopoeia or of the British Pharmaceutical Codex, and "monograph name" means, in relation to a constituent, the name which appears at the head of the relevant monograph;

"notice" means notice in writing;

"supplier" means a person selling or supplying, or procuring the sale, supply, manufacture or assembly of, a medicinal product for the purposes of a clinical trial.

(*b*) a reference to a numbered Article is to the Article of this Order bearing that number and a reference in an Article to a numbered paragraph is to the paragraph of that Article bearing that number.

(2) Section 127 of the Act applies to notices required or authorised to be given or sent by any provision of this Order as it applies to notices required or authorised to be given or sent by any provision of the Act.

(3) For the purposes of calculating any period of days referred to in this Order no account shall be taken of Christmas Day, Good Friday or a bank holiday in England under the Banking and Financial Dealings Act 1971**(a)**.

Exemption from licences and certificates in respect of clinical trials

3. Subject to the conditions in Article 4 and to the provisions of Article 5, the restrictions imposed by section 7 and section 31(2) of the Act (restrictions as to dealings in medicinal products) 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.

Conditions

4.—(1) The exemption conferred by Article 3 is subject to the conditions that—

(*a*) the supplier has given or sent to the licensing authority a notice which states his intention to sell or supply, or procure the sale, supply, manufacture or assembly of, medicinal products of the description in question for the purposes of a clinical trial and which is accompanied by—

(i) the particulars and the summaries specified in Schedule 1 to this Order;

(ii) a certificate signed by a doctor listing his medical and scientific qualifications who works within the United Kingdom and which states both that he is a medical adviser in the employment of, or consultant to, the supplier and that he has satisfied himself as to the accuracy of the summaries specified at paragraph 13 of Schedule 1 to this Order and that, having regard to the contents of those summaries, he is of the opinion that it is reasonable for the proposed clinical trial to be undertaken;

(*b*) the licensing authority have not, before the end of the specified period, given or sent to the supplier a notice stating that the provisions of this Order shall not apply to the activities proposed to be carried out by him in relation to the medicinal product; and

(a) 1971 c. 80.

(*c*) the supplier has given an undertaking to the licensing authority that he will inform them forthwith of—

(i) any adverse reactions or effects associated with the administration of the medicinal product,

(ii) any other matter coming to his attention which might reasonably cause the licensing authority to think that the medicinal product could no longer be regarded as a product which could safely be administered for the purposes of the clinical trial or as a product which was of satisfactory quality for those purposes,

(iii) any change in respect of any of the matters specified in Schedule 2 to this Order, and

(iv) any refusal to approve the clinical trial by a committee established or recognised by a health authority constituted under the National Health Service Act 1977**(a)** or, as the case may be, by a health board constituted under either the National Health Service (Scotland) Act 1978**(b)** or the Health and Personal Social Services (Northern Ireland) Order 1972**(c)** or by the Medical Research Council, to advise on the ethics of research investigations on human beings.

(2) In paragraph (1)(*b*) and Article 5(1), "the specified period" means the period of 35 days from the date on which the supplier is given or sent an acknowledgement in writing by the licensing authority that they have received the notice referred to in paragraph (1)(*a*), except that that period may be extended by the licensing authority by such further period, not exceeding 28 days, as they may determine, provided that they give or send to the supplier within the said period of 35 days a notice stating the duration of the extension.

Coming into effect, duration and termination of exemption

5.—(1) The exemption conferred by Article 3 shall take effect on the expiry of the specified period and shall continue, if the conditions specified in Article 4 are fulfilled, for a period of three years unless it is terminated in accordance with paragraphs (2) and (3).

(2) The licensing authority may, by notice given or sent to the supplier, terminate the exemption conferred by Article 3 in relation to any description of medicinal product if it appears to them that—

(*a*) medicinal products of that description can no longer be regarded as products which can safely be administered for the purposes of the clinical trial in question; or

(*b*) the specification or standards to which medicinal products of that description are manufactured can no longer be regarded as satisfactory; or

(*c*) any changes which have been notified in respect of matters specified in Schedule 2 to this Order may adversely affect the safety of a patient taking part in the clinical trial; or

(*d*) any of the matters stated in the notice referred to in Article 4(1)(*a*) or the documents which accompanied it was false or incomplete in a material particular; or

(*e*) the supplier is in breach of any part of the undertaking referred to in Article 4(1)(*c*).

(a) 1977 c. 49. The definition of "health authority" was amended by the Health Services Act 1980 (c. 53) section 1 and paragraph 77(*b*) of Part I of Schedule 1.
(b) 1978 c. 29. **(c)** S.I. 1972/1265 (N.I. 14).

(3) The date on which the termination referred to in paragraph (2) shall take effect shall be such date as may be specified by the licensing authority in the notice referred to in that paragraph.

Patrick Jenkin,
Secretary of State for Social Services.

3rd February 1981.

Nicholas Edwards,
Secretary of State for Wales.

4th February 1981.

George Younger,
Secretary of State for Scotland.

5th February 1981.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 11th day of February 1981.

(L.S.)

N. Dugdale,
Permanent Secretary.

SCHEDULE 1 Article 4(1)(*a*)(i)

Particulars and summaries which are to accompany a notice given or sent under Article 4(1)(a)

1. The name and address of the supplier and any other name under which he carries on business.

2.—(*a*) The name and address of any person taking part, in the course of a business carried on by him, in the manufacture or assembly of the medicinal product, and

(*b*) in the case of an imported product, the name and address of the manufacturer or assembler of the medicinal product in the form in which it is to be imported.

3. The name or proposed name of the medicinal product or where the medicinal product has not been given a name, the designation by which the supplier identifies that product.

4. The chemical structural formula for each active constituent. Where an active constituent is the subject of a monograph, the monograph name may be given instead of the formula.

5. A description of the pharmaceutical form in which the medicinal product is to be administered.

6. The specification of the medicinal product including a statement of its qualitative and quantitative composition giving the constituents whether active or not, and including all colouring matter, flavouring agents and perfumes.

7. In respect of each constituent, whether active or not—

(*a*) the approved name or the monograph name, or

(*b*) where there is no approved name or monograph name, a designation other than a laboratory code by which it can be readily identified.

8. A description of the containers used for the medicinal product and a statement of any special directions given by the manufacturer for storage and transport.

9. The clinical use to be investigated.

10. A description of the proposed clinical trial including the names and qualifications of each investigator, the duration of the trial, the number of patients involved, a statement of the criteria to be used in the selection for, or exclusion or withdrawal of patients from, the trial and a description of how safety will be monitored during the trial.

11. The proposed dosage and its duration, and the methods and routes of administration, of the medicinal product.

12. A summary of pharmaceutical data in respect of:—

(*a*) the method of synthesis of each active constituent and where appropriate, the results of physico-chemical tests to substantiate the structure of the compound. Where the active constituent is the subject of a monograph, the monograph name may be given instead of those data;

(*b*) the specification of each constituent whether active or not unless a specification has not been established for a constituent, in which case a batch characterisation for each batch of that constituent to be used in the clinical trial. Where a constituent is the subject of a monograph, the monograph name may be given instead of the specification;

(*c*) in the case of each constituent, whether active or not, the quality control procedures and methods to be applied to ensure compliance with the specification;

(*d*) the method of manufacture or assembly of the medicinal product;

(*e*) the procedures and methods employed and specifications used in the process of manufacture or assembly to ensure the uniformity of each medicinal product. Evidence of the stability of the medicinal product and of its bioavailability for the use intended;

(*f*) the methods to be employed during manufacture for determining the identity, purity and potency of the medicinal product and the address of the premises where such procedures are to be carried out.

13. Summaries of reports and evaluations of any experimental and biological studies and of other preclinical, clinical or laboratory studies carried out with each medicinal product or its constituents, which in the view of the supplier are relevant to the assessment of the safety, quality or efficacy of the medicinal product, together with references to relevant publications or other clinical trials.

SCHEDULE 2 Article 4(1)(*c*)(iii)

Matters in respect of which the licensing authority shall forthwith be informed of changes

1. The name or proposed name of the medicinal product or of the designation by which the medicinal product is identified.

2.—(*a*) The name and address of any person in the United Kingdom taking part, in the course of a business carried on by him, in the manufacture or assembly of the medicinal product; or

(*b*) in the case of an imported medicinal product, the name and address of the manufacturer or assembler of the medicinal product in the form in which it is imported.

3. The dosage or its duration or the methods or routes of administration, of the medicinal product.

4. The active or inactive constituents, or the method of manufacture or assembly of the medicinal product where such change will affect the bioavailability and/or the shelf life of that medicinal product.

5. The method of synthesis of any active constituent where such change will affect the range or level of impurities produced.

6. The clinical use to be investigated.

7. The criteria used in connection with the clinical trial in respect of the selection for, or exclusion or withdrawal of patients from, the trial.

8. The investigator.

9. The nature and purpose of the trial.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order grants exemption from restrictions imposed by Part II of the Medicines Act 1968 on certain dealings in medicinal products without a product licence or clinical trial certificate. The exemption, which applies where the product is for use in a clinical trial, is subject to conditions specified in the Order. Among those conditions is that there shall be submitted to the licensing authority particulars relating to the clinical trial including summaries of pharmaceutical data and of reports made and tests performed in relation to the medicinal products to be used in that trial. The Order also provides for termination of the exemption in circumstances specified in the Order.

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