STATUTORY INSTRUMENTS

1975 No. 681

MEDICINES

The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1975

Made - - - -	18*th April* 1975
Laid before Parliament	30*th April* 1975
Coming into Operation	21*st May* 1975

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 18(1) and 36(1) 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 regulations, hereby make the following regulations—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1975 and shall come into operation on 21st May 1975.

(2) These regulations shall be read as one with the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971**(c)** as amended **(d)** (hereinafter referred to as "the principal regulations").

Amendment of regulation 2 *of the principal regulations*

2. In regulation 2(1) of the principal regulations in the definition of "application" there shall be deleted all the words from "together" up to and including the words "these regulations".

Amendment of regulation 3 *of the principal regulations*

3. For regulation 3 of the principal regulations there shall be substituted the following regulation:—

"3.—(1) Every application shall be made in writing and shall be signed by the applicant for the licence, clinical trial or animal test certificate.

(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 (1969 I, p. 1070)), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c.36), and paragraph 2(1)(*b*) of Schedule 1 to the Northern Ireland Act 1974 (c. 28).

(c) S.I. 1971/973 (1971 II, p. 2816). **(d)** S.I. 1972/1201 (1972 II, p. 3560).

(2) Where the licensing authority have from time to time approved the form of applications either for use generally or in respect of particular classes of applications, every application shall be made in such approved form.

(3) Twenty-six copies, or such lesser number as the licensing authority may direct, of each application and of any accompanying particulars shall be supplied to the licensing authority in the English language and where the application or accompanying particulars have been translated from another language, also one copy of the application or the accompanying particulars, as the case may be, in the original language.

(4) An applicant for the grant of a product licence or the issue of a clinical trial or animal test certificate shall furnish to the licensing authority a separate application in respect of each medicinal product of a particular description to which such licence or certificate is intended to relate:

Provided that one application may be furnished—

(*a*) in respect of two or more medicinal products which have the same pharmaceutical form and either consist of the same single active constituent in different strengths, or consist of a mixture in different strengths of the same two or more active constituents in the same proportion,

(*b*) in respect of two or more substances or two or more articles having the same physical form and either having the same single active constituent in different strengths or being a mixture in different strengths of the same two or more active constituents in the same proportion,

(*c*) in the case of homoeopathic products and products using similar attenuations, in respect of—

(i) two or more attenuations of the same mother tincture or other solution or of the same trituration, or

(ii) two or more attenuations of any mother tincture or other solution or trituration having the same specification and pharmaceutical form apart from the tincture, solution or trituration,

(*d*) in the case of medicinal products being preparations of allergen extracts for the treatment of allergies, in respect of two or more attenuations of the same allergen extract or of the same mixture of allegen extracts,

(*e*) in the case of medicinal products for testing for allergic responses to specific substances in respect of two or more allergen extracts manufactured by one and the same method, provided that the application states the substances from which the extracts are prepared,

(*f*) in respect of two or more medicinal products to be administered to one or more patients in the course of the same clinical trial,

(*g*) in respect of two or more medicinal products, substances or articles to be administered to one or more animals in the course of the same medicinal test on animals,

(*h*) in respect of two or more medicinal products manufactured outside the United Kingdom which are to be imported and which are identified in the application by their monograph name, or which are for use as ingredients as described in paragraph (*b*) of section 130(1) of the Act, in the circumstances to which that paragraph applies, where the applicant satisfies the licensing authority that products of the same des-

cription and manufactured by the same manufacturer outside the United Kingdom have been imported into the United Kingdom within the period of 12 months ending with the date of the application, and

(*i*) where and to the extent that the licensing authority have, in the case of any particular application or any class of application, so directed.

(5) An applicant for the grant of a product licence or the issue of a clinical trial or animal test certificate shall submit the application with the pages of the application including the accompanying particulars serially numbered, and shall submit those parts of the accompanying particulars relating to—

(*a*) the chemical and pharmaceutical studies,

(*b*) the experimental and biological studies,

(*c*) the clinical studies,

(*d*) the animal tests and studies,

(*e*) particulars relating to incorporation of the medicinal product into animal feeding stuffs,

(*f*) particulars relating to possible hazards to man, live stock and wild life, and

(*g*) particulars as to precautions or contra-indications,

in so far as these are relevant to the application, each in a separate section or volume with the pages of each section or volume serially numbered separately and with the first page of each section or volume bearing a reference for identification purposes to the application of which it is a part.".

Amendment of regulation 4 *of the principal regulations*

4. In regulation 4 of the principal regulations, paragraph (1) shall be renumbered (1A) and immediately before the said paragraph there shall be inserted the following paragraph—

"(1) Except to the extent that the licensing authority have, in the case of any particular application or class of application otherwise directed, the particulars to be contained in or to accompany every application for the grant of a product licence, or the issue of a clinical trial or animal test certificate shall be those required by the succeeding paragraphs of this regulation.".

Amendment of regulation 5 *of the principal regulations*

5. After paragraph (3) of regulation 5 of the principal regulations, there shall be added the following paragraph—

"(4) Any particulars omitted under paragraph (1) of this regulation shall be subsequently furnished to the licensing authority if the licensing authority so direct and such subsequently furnished particulars shall be deemed to have been contained in or to have accompanied the application.".

Amendment of Schedule 2 *to the principal regulations*

6. In paragraph 3 of Schedule 2 to the principal regulations, the full stop at the end of sub-paragraph (*c*) shall be replaced by a comma and the following sub-paragraph shall be added—

"(*d*) to import into the United Kingdom the medicinal product for the purpose of a clinical trial.".

Amendments of Schedule 3 *to the principal regulations*

7. In paragraph 3 of Schedule 3 to the principal regulations, the full stop at the

end of sub-paragraph (*d*) shall be replaced by a comma and the following sub-paragraph shall be added:

"(*e*) to import into the United Kingdom the medicinal product for the purpose of a medicinal test on animals.".

8. In paragraph 10 of Schedule 3 to the principal regulations, for the word "after" at the beginning of the third line there shall be substituted the word "for".

Barbara Castle,
Secretary of State for Social Services.

27th March 1975.

John Morris,
Secretary of State for Wales.

8th April 1975.

William Ross,
Secretary of State for Scotland.

9th April 1975.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 10th April 1975.

(L.S.)

Frederick Peart,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 14th day of April 1975.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 18th day of April 1975.

(L.S.)

J. A. Young,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations amend the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 with regard to the details required to be submitted to the licensing authority by applicants for product licences, clinical trial certificates and animal test certificates so as to allow the licensing authority to accept applications in less detail than that provided for under the 1971 regulations.

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