STATUTORY INSTRUMENTS

1972 No. 1201

MEDICINES

The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1972

Made - - -	*4th August* 1972
Laid before Parliament	*11th August* 1972
Coming into Operation	*1st September* 1972

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 Secretary of State for Northern Ireland and the Minister of Agriculture, Fisheries and Food, acting jointly, in exercise of their powers under sections 18, 36 and 129(1) of the Medicines Act 1968(**a**) (as having effect subject to the provisions of Article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969(**b**) and section 1(1)(*a*) of the Northern Ireland (Temporary Provisions) Act 1972(**c**)) 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 regulations, hereby make the following regulations:—

Citation, interpretation and commencement

1. These regulations, which may be cited as the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1972 shall be read as one with the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971(**d**) (hereinafter referred to as "the principal regulations"), and shall come into operation on 1st September 1972.

Amendment of regulation 3 *of the principal regulations*

2.—(1) Regulation 3(1) of the principal regulations shall be amended as follows:—

(*a*) for paragraph (*c*) of the proviso there shall be substituted the following paragraph:—

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

(i) two or more attenuations of the same mother tinctures or other solutions or of the same triturations, or

(ii) two or more attenuations of any mother tinctures or other solutions or triturations having the same specification and pharmaceutical form apart from the tinctures, solutions, or triturations,";

(**a**) 1968 c. 67.
(**b**) S.I. 1969/388 (1969 I, p. 1070).
(**c**) 1972 c. 22.
(**d**) S.I. 1971/973 (1971 II, p. 2816).

(*b*) at the end of the proviso there shall be added the following paragraphs:—

"(*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; and

(*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*) 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 description 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.".

(2) After paragraph (4) of regulation 3 of the principal regulations there shall be added the following paragraph:—

"(5) Subject to the requirements of paragraph (1), an applicant, being the proposed licensee, may furnish to the licensing authority in the form of a single document signed by him any number of applications, which need not be signed separately as required by paragraph (4), where such applications are in respect of medicinal products for which product licences, including product licences of right, are held by a person other than the applicant and the right to all dealings to which the applications relate in those medicinal products have been assigned, sold or otherwise transferred by that other person to the applicant.".

Keith Joseph,
Secretary of State for Social Services.

28th July 1972.

Peter Thomas,
Secretary of State for Wales.

1st August 1972.

Gordon Campbell,
Secretary of State for Scotland.

3rd August 1972.

W. S. I. Whitelaw,
Secretary of State for Northern Ireland.

3rd August 1972.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th August 1972.

(L.S.)

J. M. L. Prior,
Minister of Agriculture, Fisheries and Food.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These Regulations amend regulation 3 of the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 by extending the circumstances in which one application may be furnished for the grant of product licences or clinical trial or animal test certificates in respect of more than one medicinal product, substance or article, and specifying the circumstances in which more than one application for a product licence may be included in a single document.

SI 1972/1201
ISBN 0-11-021201-0