STATUTORY INSTRUMENTS

1992 No. 755

MEDICINES

The Medicines (Applications for Grant and Renewal of Licences) (Miscellaneous Amendments) Regulations 1992

Made - - - -	*12th March 1992*
Laid before Parliament	*13th March 1992*
Coming into force - -	*3rd April 1992*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and 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 upon them by sections 18 (including that section as read with section 24(4) of that Act) and 129(1) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said 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 these Regulations(**3**), hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Applications for Grant and Renewal of Licences) (Miscellaneous Amendments) Regulations 1992, and shall come into force on 3rd April 1992.

(2) In these Regulations—

(a) "the Principal Regulations" means the Medicines (Applications for Product Licences and Clinical Trial Certificates and Animal Test Certificates) Regulations 1971(**4**); and

(**1**) 1968 c. 67. The expression "the Ministers" is defined in section 1(1) of that Act as amended.

(**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; in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I.1978/272); 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 section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28). For the application of certain sections of the Medicines Act 1968 to radiopharmaceutical products *see* S.I. 1992/605.

(**3**) *See* section 129(6) of the Medicines Act 1968 (c. 67).

(**4**) S.I. 1971/973; the relevant amending instruments are S.I. 1975/681, 1977/1051, 1983/1726.

(b) "the Renewal Regulations" means the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974(**5**).

Amendment of regulation 2(1) of the Principal Regulations

2. In regulation 2(1) of the Principal Regulations (interpretation)—

(a) after the definition of "the Act" there shall be inserted the following:—

""allergen product" means any product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergising agent;"

(b) after the definition of "approved name" there shall be inserted the following:—

""blood product" means any industrially prepared medicinal product for human use derived from human blood or human plasma and includes albumin, coagulating factors and immunoglobulins of human origin, but does not include whole human blood, human plasma or blood cells of human origin;";

(c) after the definition of "clinical trial certificate" and "animal test certificate" there shall be inserted—

""generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and used in a radiopharmaceutical;";

(d) at the end of the definition of "medicinal product" there shall be added the words "and any generator, kit or precursor as defined in regulation 1(2) of the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992"(**6**);

(e) after the definition of "proprietary medicinal product" and "ready-made veterinary drug", there shall be inserted the following:—

""radiopharmaceutical" means any medicinal product for human use which, when ready for use, contains one or more radioactive isotopes which are included for a medicinal purpose;";

(f) after the definition of "standard provisions for licences and certificates" there shall be inserted—

""vaccine", "toxin" and "serum" means any such product for human use and include any agent which is used—

(a) to produce active immunity;

(b) to diagnose immunity; or

(c) to produce passive immunity.".

Insertion of regulation 4A into the Principal Regulations

3. After regulation 4 of the Principal Regulations there shall be inserted the following regulation:—

"**Further requirements as respects the particulars to be contained in or accompany an application for the grant of a product licence for products for human use**

4A. In addition to the material required by regulation 4 of these Regulations to be contained in or to accompany an application for the grant of a product licence any such application—

(**5**) S.I. 1974/832; the relevant amending instrument is S.I. 1982/1789.
(**6**) S.I. 1992/605.

(a) relating to a blood product, shall comply with the requirements specified in Part I of Schedule 1A to these regulations;

(b) relating to a vaccine, toxin, serum or allergen product, shall comply with the requirements of Part II of that Schedule;

(c) relating to a radiopharmaceutical, shall comply with the requirements of Part III of that Schedule.".

Insertion of Schedule 1A to the Principal Regulations

4. After Schedule 1 to the Principal Regulations there shall be inserted the following Schedule—

"SCHEDULE 1A Regulation 4A

REQUIREMENTS AS TO THE PARTICULARS ON AN APPLICATION FOR THEGRANT OF A PRODUCT LICENCE IN RESPECT OF CERTAIN PRODUCTS

PART I

BLOOD PRODUCTS

1. In the particulars required by Part I or Part II of Schedule I to these Regulations the common or scientific name of the active constituents shall be mentioned at least once (though they may be abbreviated in other references).

2. The statement required by paragraph 12 of Part I of, or by paragraph 13 of Part II of Schedule 1 to these Regulations shall—

(a) as respects quantitative composition, be expressed by mass, by international units or by units of biological activity as appropriate to the product;

(b) include particulars relating to biological activity and shall include the composition of the product (expressed in accordance with sub-paragraph (a) of this paragraph).

PART II

VACCINES, TOXINS, SERUMS, OR ALLERGEN PRODUCTS

1. The name or proposed name of the product under which the product is to be sold or supplied shall include the common or scientific name of the active constituents.

2. The statement of qualitative and quantitative composition shall include particulars relating to biological activity or to protein content and the statement of the composition of the product shall be expressed in terms either of biological activity or of protein content.

3. The statement of the quantitative particulars shall be expressed by mass, in international units, by units of biological activity or by specific protein content as appropriate to the product concerned.

4. The particulars shall include a description of any special precautions to be taken by persons handling the product and persons administering the product to patients together with any precautions to be taken by the patient.

PART III

RADIOPHARMACEUTICALS

The particulars shall include—

(a) a statement of the details of internal radiation dosimetry;

(b) a statement specifying the instructions for extemporaneous preparation and quality control of the product and where appropriate, maximum storage time during which any intermediate preparation or the completed product will conform with its specifications; and

(c) if the application is in respect of a radiopharmaceutical which is a generator—

(i) a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter nuclide preparation; and

(ii) qualitative and quantitative particulars of the eluate or the sublimate.".

Amendment of regulation 1(2) of the Renewal Regulations

5. Regulation 1(2) of the Renewal Regulations (interpretation) shall be amended as follows—

(a) after the definition of "the Act" there shall be inserted the following—

""allergen product" means any product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergising agent;and "blood product" means any industrially produced medicinal product for human use derived from human blood or human plasma and includes albumin, coagulating factors and immunoglobulins of human origin but does not include whole human blood, human plasma or blood cells of human origin;";

(b) after the definition of "certificate" there shall be inserted the following—

""generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and used in a radiopharmaceutical;";

(c) after the definition of "medicinal product" there shall be inserted the following—

""radiopharmaceutical" means any medicinal product for human use which, when ready for use, contains one or more radioactive isotopes which are included for a medicinal purpose;";

(d) after the definition of "renewal application" there shall be inserted the following—

""vaccine", "toxin" and "serum" mean any such product for human use and include any agent which is used—

(a) to produce active immunity;

(b) to diagnose immunity; or

(c) to produce passive immunity.".

Insertion of regulation 5A into the Renewal Regulations

6. After regulation 5 of the Renewal Regulations there shall be inserted the following regulation—

"**Further requirements as respects the particulars to be contained in or accompany an application for the renewal of a product licence for products for human use**

5A. The particulars which, by regulations 4 and 5 of, and the Schedule to, these Regulations, are required to be contained in or to accompany an application for the renewal of a product licence shall—

(a) if they relate to a blood product, comply with the provisions of Part III of the Schedule to these Regulations;

(b) if they relate to a vaccine, toxin, serum or allergen product, comply with the provisions of Part IV of that Schedule;

(c) if they relate to a radiopharmaceutical, comply with the provisions of Part V of that Schedule.".

Insertion of Parts III, IV and V into the Schedule to the Renewal Regulations

7. After Part II of the Schedule to the Renewal Regulations, there shall be inserted the following—

"PART III

FURTHER PROVISIONS AS TO THE PARTICULARS WHICH ARE TO BE CONTAINED IN OR ACCOMPANY AN APPLICATION FOR THE RENEWAL OF A PRODUCT LICENCE IN RESPECT OF BLOOD PRODUCTS FOR HUMAN USE

1. In the particulars required by Part I or Part II of this Schedule the common or scientific name of the active constituents shall be mentioned at least once (though they may be abbreviated in other references

2. The statement required by paragraph 5(a) and (b) of Part I of, or by paragraph 7(a) and (b) of Part II of this Schedule shall

(a) as respects quantitative composition, be expressed by mass, by international units or by units of biological activity as appropriate to the product;

(b) include particulars relating to biological activity and shall include the composition of the product (expressed in accordance with sub-paragraph (a) of this paragraph).

PART IV

FURTHER PROVISIONS AS RESPECTS THE PARTICULARS TO BE CONTAINED IN OR ACCOMPANY AN APPLICATION FOR THE RENEWAL OF A PRODUCT LICENCE FOR A VACCINE, TOXIN, SERUM OR ALLERGEN PRODUCT FOR HUMAN USE

1. The particulars required by paragraph 4 of Part I of, or by paragraph 7(a) and (b) of Part II of this Schedule shall include the name or proposed name of the product under which the product is to be sold or supplied which shall include the common or scientific name of the active constituents.

2. The particulars of qualitative and quantitative composition shall include particulars relating to biological activity or to protein content; and the statement of the composition of the product shall be expressed in terms either of biological activity or of protein content.

3. The statement of quantitative particulars shall be expressed by mass, in international units, by units of biological activity or by specific protein content as appropriate to the product concerned.

4. The particulars shall include a description of any special precautions to be taken by persons handling the product and persons administering the product to patients together with any precautions to be taken by the patient.

PART V

FURTHER REQUIREMENTS AS RESPECTS THE PARTICULARS WHICH ARE TO BE CONTAINED IN OR ACCOMPANY AN APPLICATION FOR THE RENEWAL OF A PRODUCT LICENCE FOR A RADIOPHARMACEUTICAL FOR HUMAN USE

The particulars required by paragraphs 5(a) and (c) of Part I of, or by paragraph 7(a) and (c) of Part II of the Schedule to these Regulations shall include—

(a) a statement of the details of internal radiation dosimetry;

(b) a statement specifying the instructions for extemporaneous preparation and quality control of the product and where appropriate, maximum storage time during which any intermediate preparation or the completed product will conform with its specifications; and

(c) if the application is in respect of a radiopharmaceutical which is a generator—

(i) a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter nuclide preparation; and

(ii) qualitative and quantitative particulars of the eluate or the sublimate.”.

Signed by authority of the Secretary of State for Health

Virginia Bottomley
Minister of State,
12th March 1992 Department of Health

David Hunt
12th March 1992 Secretary of State for Wales

Michael Forsyth
12th March 1992 Minister of State for Scotland

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 12th March 1992.

L.S.

Derek Andrews
Permanent Secretary Ministry of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 12th March 1992.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 12th March 1992.

L.S.

W. J. Hodges
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Applications for Product Licences and Clinical Trial Certificates and Animal Test Certificates) Regulations 1971 and the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974 by adding to the requirements as to particulars to be contained in, or to accompany, an application for the grant or renewal of a product licence, so implementing in part Council Directives—

89/342/EEC relating to immunological products (OJNo. L142, 25.5.1989, p.14) (Regulations 2(a), 2(b), 3 and 4 which implement articles 1, 2 and 3 of that Directive);

89/343/EEC relating to radiopharmaceuticals (OJ No. L142, 25.5.1989, p.16) (Regulations 2(c), 3 and 4 which implement in part articles 1, 2, 3 and 4 of that Directive); and

89/381/EEC relating to medicinal products derived from human blood or human plasma (OJ No. L181, 28.6.1989, p.44) (Regulations 2(a), 3 and 4 which implement articles 1 and 2 of that Directive);

by imposing special conditions for applications for product licences in respect of these types of product.

These Directives extend the scope of Council Directives 65/65/EEC (OJ No. 22, 9.2.1965 p.369/65) and 75/319/EEC (OJ No. L147, 9.6.1975, p.13) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, to cover such products which had previously been excluded byArticle 34 of Council Directive 75/319/EEC.