STATUTORY INSTRUMENTS

1971 No. 973

MEDICINES

The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971

Made - - -	*9th June* 1971
Laid before Parliament	*24th June* 1971
Coming into Operation	*1st July* 1971

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 Health and Social Services for Northern Ireland, the Minister of Agriculture, Fisheries and Food and the Minister of Agriculture for Northern Ireland, 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 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, hereby make the following regulations :—

Citation and commencement

1. These regulations may be cited as the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 and shall come into operation on 1st July 1971.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—

"the Act" means the Medicines Act 1968 ;

"application" means a request for the grant of a product licence (other than a product licence of right) or the issue of a clinical trial certificate or animal test certificate (other than a clinical trial certificate or animal test certificate issued under section 37(4) of the Act) together with particulars of the product or products which may be the subject of one request in accordance with regulation 3 of these regulations, but does not include a request to renew a product licence or a clinical trial certificate or animal test certificate ;

"approved name" in relation to a constituent is 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 ;

(**a**) 1968 c. 67. (**b**) S.I. 1969/388 (1969 I, p. 1070).

"clinical trial certificate" and "animal test certificate" do not include certificates to which an applicant is entitled who satisfies the requirements of section 37(4) of the Act;

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

"product licence" does not include a product licence of right;

"proprietary designation" means a word or words used or proposed to be used in connection with the sale of a medicinal product, substance or article or constituent for the purpose of indicating that they are the goods of a particular person by virtue of manufacture, selection, certification, dealing with or offering for sale;

"standard provisions for licences or certificates" mean those provisions prescribed by the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**a**)

and other expressions have the same meaning as in the Act.

(2) The Interpretation Act 1889(**b**) shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

Form and manner of application

3.—(1) An applicant for the grant of a product licence or a clinical trial or an animal test certificate shall furnish to the licensing authority a separate application in respect of each medicinal product of a particular description, and in respect of each substance or article:

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 two or more attenuations of the same mother tincture or other solution or of the same 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 allergen extracts, and

(*e*) in the case of medical 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.

(**a**) S.I. 1971/972 (1971 II, p. 2809). (**b**) 1889 c. 63.

(2) An applicant for the grant of a product licence or a clinical trial or an animal test certificate shall supply the licensing authority with six copies in the English language of his application and of the accompanying particulars and where the application or accompanying particulars have been translated from another language also one copy of the application or the particulars as the case may be in their original language. An applicant shall supply the licensing authority at its request with up to twenty additional copies of the application and any accompanying particulars.

(3) An applicant for the grant of a product licence or a clinical trial or an 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 the chemical and pharmaceutical studies, to the experimental and biological studies and to the clinical studies 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.

(4) An application for a product licence or a clinical trial or an animal test certificate shall be signed by the applicant and where an application is made by a person other than the proposed licensee or certificate holder the application shall be signed also by the proposed licensee or certificate holder.

Material to be contained in or to accompany an application

4.—(1) Every application for the grant of a product licence for a medicinal product, substance or article other than those to which the succeeding paragraphs of this regulation apply, shall contain or be accompanied by the particulars specified in Part I of Schedule 1 to these regulations.

(2) Every application for the grant of a product licence in so far as it relates to the sale, supply or exportation, or to the procurement of the sale, supply or exportation of

(*a*) an imported medicinal product, or

(*b*) an imported substance or article not previously sold or supplied for a medicinal purpose in the United Kingdom,

shall contain or be accompanied by the particulars specified in Part II of Schedule 1 to these regulations.

(3) Every application for the grant of a product licence to import a medicinal product for use by the importer for administration to animals or incorporation in any animal feeding stuff for a medicinal purpose, shall contain or be accompanied by the particulars specified in Part III of Schedule 1 to these regulations.

(4) Any person who—

(*a*) in the course of business carried on by him proposes—

(i) to sell or to supply a substance or article other than a medicinal product to persons who for a medicinal purpose may require to incorporate it in any animal feeding stuff to be fed to animals, or

(ii) to manufacture such a substance or article for sale or supply to persons who for a medicinal purpose may require to incorporate it in any animal feeding stuff to be fed to animals,

(*b*) proposes by purchase or otherwise to obtain from such a person as is first mentioned in each of the preceding sub paragraphs (*a*)(i) and (*a*)(ii), a supply of a substance or article other than a medicinal product with a view to incorporating it for a medicinal purpose in any animal feeding stuff to be fed to animals,

and who desires to apply for the grant of a product licence, shall furnish with his application the particulars specified in Part IV of Schedule 1 to these regulations.

(5) Every application for the issue of a clinical trial certificate shall contain or be accompanied by the particulars specified in Schedule 2 to these regulations.

(6) Every application for the issue of an animal test certificate shall contain or be accompanied by the particulars specified in Schedule 3 to these regulations.

Supplementary provisions as to application

5.—(1) Where, in any application for the grant of a product licence or the issue of a clinical trial or an animal test certificate in accordance with these regulations, any required particulars are not furnished, the application shall state

(*a*) that the required particulars are not applicable, or

(*b*) any other reason for their absence.

(2) Every application for the grant of a product licence or the issue of a clinical trial or an animal test certificate shall specify which, if any, of the standard provisions for licences or certificates it is desired shall be excluded or modified in relation to the grant of the licence or the issue of the certificate.

(3) Every applicant for the grant of a product licence or the issue of a clinical trial or an animal test certificate shall supply the licensing authority with a sample of the medicinal product or substance or article to which the application relates if requested to do so by the licensing authority for the purpose of determining the application.

Keith Joseph,
Secretary of State for Social Services.

19th May 1971.

Given under my hand on 20th May 1971.

Peter Thomas,
Secretary of State for Wales.

Given under my hand on 25th May 1971.

Gordon Campbell,
Secretary of State for Scotland.

Given under my hand on 4th June 1971.

W. K. Fitzsimmons,
Minister of Health and Social Services
for Northern Ireland.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 27th May 1971.

(L.S.)

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

Given under my hand on 9th June 1971.

H. W. West,
Minister of Agriculture for Northern Ireland.

Regulation 4(1)

SCHEDULE 1

PART I

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A PRODUCT LICENCE—

(*a*) FOR A MEDICINAL PRODUCT MANUFACTURED OR ASSEMBLED IN THE UNITED KINGDOM, OR

(*b*) FOR A SUBSTANCE OR ARTICLE NOT PREVIOUSLY SOLD OR SUPPLIED FOR A MEDICINAL PURPOSE

(i) WHERE MANUFACTURED IN THE UNITED KINGDOM, OR

(ii) WHERE THE PROPOSED LICENSEE DOES NOT KNOW WHETHER IT WAS MANUFACTURED IN, OR IMPORTED INTO, THE UNITED KINGDOM, OR

(*c*) FOR ANY OTHER MEDICINAL PRODUCT, SUBSTANCE OR ARTICLE OTHER THAN THOSE TO WHICH THE SUCCEEDING PARTS OF THIS SCHEDULE APPLY.

Particulars relating to the applicant and licensee and the type and purpose of the licence

1. The name and address of the applicant, and, where the applicant is not the proposed licensee, the name and address of the proposed licensee, being the person responsible for the composition of the medicinal product for the purposes of section 7(5) and (6) of the Act.

2. Where the provisions of section 43 of the Act apply, the name and address of the person who proposes to sell, supply or export the substance or article for use as a medicinal product, and a statement as to whether the person is engaged in retail sale or in supply in circumstances corresponding to retail sale and has assembled or proposes to assemble the substance or article for the purposes of being sold or supplied by him for a medicinal purpose.

3. The period for which the licence is desired, where it is for less than five years.

4. A statement of the activities to which the licence is to relate, that is to say, whether it is one or more of the following—

(*a*) to sell or supply the medicinal product or the substance or article in the United Kingdom,

(*b*) to procure the sale or supply by another person of the medicinal product or the substance or article in the United Kingdom,

(*c*) to export the medicinal product or the substance or article,

(*d*) to procure the exportation by another person of the medicinal product or the substance or article,

(*e*) to procure the manufacture or assembly by another person of the medicinal product or the substance or article for the purposes of any of the activities referred to in sub paragraphs (*a*), (*b*), (*c*) or (*d*) of this paragraph.

5. A statement of the use for which the medicinal product or the substance or article is to be manufactured, sold, supplied or exported, and whether the use is as stated in one or more of the following subparagraphs—

(*a*) for use by being administered to human beings,

(*b*) for use by being administered to animals,

(*c*) for use in the form of an ingredient in the preparation of a substance or article which is to be administered to human beings or animals for a medicinal purpose,

(*d*) for use by incorporation in any animal feeding stuff.

6. A description of the contemplated method of sale or supply in the United Kingdom.

7. (*a*) A statement of the manufacturing or assembling operations relating to the medicinal product or the substance or article to be carried out by the proposed licensee or any other persons, and

(*b*) a statement of the address of each place or proposed place of manufacture or assembly, and

(*c*) the name and address of the persons, if any, other than the proposed licensee proposing to take part in the manufacture or assembly and a statement of the operations for which each such person is to be responsible, and

(*d*) a statement of the arrangements made or proposed for storage of the medicinal product by the proposed licensee or on his behalf, and

(*e*) a statement of the address of each place or proposed place of storage of the medicinal product by the proposed licensee or on his behalf.

8. Where the activity to which a licence is to relate is—

(*a*) to procure the sale or supply by another person of the medicinal product or the substance or article in the United Kingdom, or

(*b*) to procure the exportation by another person of the medicinal product or the substance or article,

the name and address of the person who is to sell, supply or export the medicinal product or the substance or article.

Particulars relating to the product

9. The name or proposed name under which the medicinal product or the substance or article will be sold, supplied or exported.

10. A statement of the specification of the medicinal product or of the substance or article other than as required by paragraphs 11, 12 and 14 of this part of this Schedule.

11. A description of the pharmaceutical form of the medicinal product or the substance or article.

12. A statement of the qualitative and quantitative composition of the medicinal product or the substance or article covering—

(*a*) all active constituents,

(*b*) all colouring matter, flavouring agents and perfumes, and

(*c*) all other constituents.

13. 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, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub paragraph (*a*) and (*b*) of this paragraph, the proprietary designation.

14. The specification of all constituents whether active or not. Where the constituent is the subject of a monograph, a reference to the monograph name may be given instead of the specification.

15. The chemical structural formula for each active constituent where known. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of the formula.

16. A description of the method of manufacture or assembly of the medicinal product or the substance or article.

17. A description of the method of manufacture of each active constituent. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of a description.

18. A statement whether precautions will be taken during manufacture or assembly to control the quality of the medicinal product or the substance or article and whether the proposed licensee will be responsible for deciding that any batch of the medicinal product or the substance or article is of acceptable quality for sale, supply or exportation, and, if not, who will be responsible.

19. In the case of all constituents, whether active or not, a description of the quality control procedures and methods to be applied to ensure compliance with the specification.

20. A description of the procedures or methods to be used to ensure the uniformity of the medicinal product or the substance or article in the process of manufacture or assembly, and evidence of the stability and the grounds for any proposed shelf-life of the medicinal product or the substance or article.

21. Particulars of the methods to be employed during manufacture or assembly for determining the identity, purity and potency of the medicinal product or the substance or article and the address of the premises where such procedures are to be carried out.

22. A description of the nature of the containers to be used for the medicinal product or the substance or article and a statement of any special directions necessary for storage and transport.

23. In the case of a licence relating to a medicinal product or a substance or article to be incorporated in any animal feeding stuff—

(*a*) a description of the feeding stuff, and

(*b*) data on any relevant compatibilities or incompatibilities of the medicinal product or the substance or article known to the proposed licensee with other substances or articles, on its stability in animal feeding stuffs and on methods of incorporation and rates of inclusion in animal feeding stuffs, and

(*c*) a description of the method of analysis used to determine whether or not the medicinal product or the substance or article has been correctly incorporated, and to determine the rates of inclusion in animal feeding stuffs.

24. Particulars of the indications suggested by the proposed licensee for the administration of the medicinal product or the substance or article, whether or not incorporated in an animal feeding stuff.

25. Particulars of the proposed dose or dosage, methods and routes of administration.

26. Any directions, contra-indications and warnings proposed, and the basic particulars of the information proposed to be included on the container label, on the package label and in any leaflet to be inserted in the package, or in other informative literature.

27. Copies of reports and evaluations of any experimental and biological studies and of other preclinical, clinical or laboratory studies carried out with the medicinal product or the substance or article or its constituents which, in the view of the proposed licensee, are relevant to the assessment of the safety, quality or efficacy of the medicinal product or the substance or article, together with references to relevant publications, clinical trial or animal test certificates.

PART II — Regulation 4(2)

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A PRODUCT LICENCE

(*a*) FOR AN IMPORTED MEDICINAL PRODUCT, OR

(*b*) FOR AN IMPORTED SUBSTANCE OR ARTICLE NOT PREVIOUSLY SOLD OR SUPPLIED FOR A MEDICINAL PURPOSE IN THE UNITED KINGDOM.

Particulars relating to the applicant and licensee and the purpose of the licence

1. The name and address of the applicant, and, where the applicant is not the proposed licensee, the name and address of the proposed licensee, being the person who has, or will have, procured the importation of the imported medicinal product, or the imported substance or article.

2. Where the provisions of section 43 of the Act apply, the name and address of the person who proposes to sell, supply or export the substance or article for use as a medicinal product, and a statement as to whether the person is engaged in retail sale or in supply in circumstances equivalent to retail sale and has assembled or proposes to assemble the substance or article for the purpose of being sold or supplied by him for a medicinal purpose.

3. The name and address of the importer of the medicinal product or the substance or article.

4. The period for which the licence is desired, where it is for less than five years.

5. A statement of the activities to which the licence is to relate, and whether it is one or more of the following—

(*a*) to sell or supply the medicinal product or the substance or article in the United Kingdom,

(*b*) to procure the sale or supply by another person of the medicinal product or the substance or article in the United Kingdom,

(*c*) to export the medicinal product or the substance or article,

(*d*) to procure the exportation by another person of the medicinal product or the substance or article,

(*e*) to procure the manufacture or assembly by another person of the medicinal product or the substance or article for the purposes of any of the activities referred to in sub paragraphs (*a*), (*b*), (*c*) or (*d*) of this paragraph.

6. A statement of the use for which the medicinal product or the substance or article is to be imported, manufactured, sold, supplied or exported, and whether the use is as stated in one or more of the following subparagraphs—

(*a*) for use by being administered to human beings,

(*b*) for use by being administered to animals,

(*c*) for use in the form of an ingredient in the preparation of a substance or article which is to be administered to human beings or animals for a medicinal purpose,

(*d*) for use by incorporation in any animal feeding stuff.

7. A description of the contemplated method of sale or supply in the United Kingdom.

8. (*a*) The name and address of the manufacturer or assembler of the medicinal product or the substance or article in the form in which it will be imported,

(*b*) (i) a statement of the manufacturing or assembling operations relating to the medicinal product or the substance or article carried out or to be carried out in the United Kingdom or elsewhere by the proposed licensee or any other persons, and

(ii) a statement of the address of each place or proposed place of manufacture or assembly in the United Kingdom, and

(iii) the name and address of the persons, if any, other than the proposed licensee taking part or proposing to take part in the manufacture or assembly in the United Kingdom or elsewhere and a statement of the operations for which each such person is to be responsible, and

(iv) a statement of the arrangements made or proposed for storage of the medicinal product by the proposed licensee or on his behalf, and

(v) a statement of the address of each place or proposed place of storage of the medicinal product by the proposed licensee or on his behalf.

9. Where the activity to which the licence is to relate is—

(*a*) to procure the sale or supply by another person of the medicinal product or the substance or article in the United Kingdom, or

(*b*) to procure the exportation by another person of the medicinal product or the substance or article,

the name and address of the person who is to sell, supply or export the medicinal product or the substance or article.

Particulars relating to the product

10. The name or proposed name under which the medicinal product or the substance or article will be sold, supplied or exported.

11. A statement of the specification of the medicinal product or of the substance or article other than as required by paragraphs 12, 13 and 15 of this part of this Schedule.

12. A description of the pharmaceutical form of the medicinal product or the substance or article.

13. A statement of the qualitative and quantitative composition of the medicinal product or the substance or article covering—

(*a*) all active constituents,

(*b*) all colouring matter, flavouring agents and perfumes, and

(*c*) all other constituents.

14. 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, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub paragraphs (*a*) and (*b*) of this paragraph, the proprietary designation.

15. The specification of all constituents whether active or not. Where the constituent is the subject of a monograph, a reference to the monograph name may be given instead of the specification.

16. The chemical structural formula for each active constituent where known. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of the formula.

17. A description of the method of manufacture or assembly of the medicinal product or the substance or article both before and after importation.

18. A description of the method of manufacture of each active constituent both before and after importation. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of a description.

19. A statement whether precautions will be taken during manufacture or assembly both before and after importation to control the quality of the medicinal product or the substance or article and whether the proposed licensee will be responsible for deciding that any batch of the medicinal product or the substance or article is of acceptable quality for sale, supply or exportation, and, if not, who will be responsible.

20. In the case of all constituents, whether active or not, a description of the quality control procedures and methods to be applied both before and after importation to ensure compliance with the specification.

21. A description of the procedures or methods to be used both before and after importation to ensure the uniformity of the medicinal product or the substance or article in the process of manufacture or assembly, and evidence of the stability and the grounds for any proposed shelf-life of the medicinal product or the substance or article.

22. Particulars of the methods to be employed during manufacture or assembly both before and after importation for determining the identity, purity and potency of the medicinal product or the substance or article, and the address of the premises where such procedures are to be carried out.

23. A description of the nature of the containers to be used for the medicinal product or the substance or article, and a statement of any special directions necessary for storage and transport.

24. In the case of a licence relating to a medicinal product or a substance or article to be incorporated in any animal feeding stuff—

(*a*) a description of the feeding stuff, and

(*b*) data on any relevant compatibilities or incompatibilities of the medicinal product or the substance or article known to the proposed licensee with other substances or articles, on its stability in animal feeding stuffs and on methods of incorporation and rates of inclusion in animal feeding stuffs, and

(*c*) a description of the method of analysis used to determine whether or not the medicinal product or the substance or article has been correctly incorporated, and to determine the rates of inclusion in animal feeding stuffs.

25. Particulars of the indications suggested by the proposed licensee for the administration of the medicinal product or the substance or article, whether or not incorporated in an animal feeding stuff.

26. Particulars of the proposed dose or dosage, methods and routes of administration.

27. Any directions, contra-indications and warnings proposed, and the basic particulars of the information proposed to be included on the container label, on the package label and in any leaflet to be inserted in the package, or in other informative literature.

28. Copies of reports and evaluations of any experimental and biological studies and of other preclinical, clinical or laboratory studies carried out with the medicinal product or the substance or article or its constituents which in the view of the proposed licensee are relevant to the assessment of the safety, quality or efficacy of the medicinal product or the substance or article, together with references to relevant publications, clinical trial or animal test certificates.

Regulation 4(3) PART III

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A PRODUCT LICENCE TO IMPORT A MEDICINAL PRODUCT FOR USE BY THE IMPORTER BY BEING ADMINISTERED TO ANIMALS OR INCORPORATED IN ANY ANIMAL FEEDING STUFF FOR A MEDICINAL PURPOSE

Particulars relating to the applicant and licensee and the purpose of the licence

1. The name and address of the applicant, and, where the applicant is not the proposed licensee, the name and address of the proposed licensee, namely the importer of the medicinal product.

2. The period for which the licence is desired, where it is for less than five years.

3. A statement of the purpose in relation to which the medicinal product is to be imported, and whether it is—

(*a*) for use by being administered to animals, or

(*b*) for incorporation in any animal feeding stuff.

4. (*a*) The name and address of the manufacturer or assembler of the medicinal product in the form in which it will be imported, and

(*b*) the name and address of any person in the United Kingdom other than the licensee taking part in the manufacture or assembly of the medicinal product after importation, and

(*c*) a statement of the arrangements made or proposed for storage of the medicinal product by the proposed licensee or on his behalf, and

(*d*) a statement of the address of each place or proposed place of storage of the medicinal product by the proposed licensee or on his behalf.

Particulars relating to the medicinal product

5. The name of the medicinal product to be imported.

6. A statement of the specification of the medicinal product other than as required by paragraphs 7, 8 and 10 of this part of this Schedule.

7. A description of the pharmaceutical form in which the medicinal product is to be administered to animals, or is for use by incorporation in any animal feeding stuff.

8. A statement of the qualitative and quantitative composition of the medicinal product covering—

(*a*) all active constituents,

(*b*) all colouring matter, flavouring agents and perfumes, and

(*c*) all other constituents.

9. 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, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub paragraphs (*a*) and (*b*) of this paragraph, the proprietary designation.

10. The specification of all constituents whether active or not. Where the constituent is the subject of a monograph, a reference to the monograph name may be given instead of the specification.

11. The chemical structural formula for each active constituent where known. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of the formula.

12. A description of the method of manufacture or assembly of the medicinal product both before and after importation.

13. A description of the method of manufacture of each active constituent both before and after importation. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of a description.

14. A statement whether precautions will be taken during manufacture or assembly both before and after importation to control the quality of the medicinal product and whether the proposed licensee will be responsible for deciding that any batch of the medicinal product is of acceptable quality for sale, supply or exportation, and, if not, who will be responsible.

15. In the case of all constituents whether active or not, a description of the quality control procedures and methods to be applied both before and after importation to ensure compliance with the specification.

16. A description of the procedures or methods to be used both before and after importation to ensure the uniformity of the medicinal product in the process of manufacture or assembly, and evidence of the stability and the grounds for any proposed shelf-life of the medicinal product.

17. Particulars of the methods to be employed during manufacture or assembly both before and after importation 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.

18. A description of the nature of the containers to be used for the medicinal product and a statement of any special directions necessary for storage and transport.

19. In the case of a licence relating to a medicinal product to be incorporated in any animal feeding stuff—

(*a*) a description of the feeding stuff, and

(*b*) data on any relevant compatibilities or incompatibilities of the medicinal product known to the proposed licensee with other substances or articles, on its stability in animal feeding stuffs and on methods of incorporation and rates of inclusion in animal feeding stuffs, and

(*c*) a description of the method of analysis used to determine whether or not the medicinal product has been correctly incorporated, and to determine the rates of inclusion in animal feeding stuffs.

20. Particulars of the indications suggested by the proposed licensee for the administration of the medicinal product whether or not incorporated in an animal feeding stuff.

21. Particulars of the proposed dose or dosage, methods and routes of administration.

22. Copies of reports and evaluations of any experimental and biological studies and of other preclinical, clinical or laboratory studies carried out with the medicinal product or its constituents which in the view of the proposed licensee are relevant to the assessment of the safety, quality or efficacy of the medicinal product, together with references to relevant publications, clinical trial or animal test certificates.

Regulation 4(4)

PART IV

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A PRODUCT LICENCE FOR A SUBSTANCE OR ARTICLE OTHER THAN A MEDICINAL PRODUCT INTENDED FOR INCORPORATION IN ANIMAL FEEDING STUFFS FOR A MEDICINAL PURPOSE

Particulars relating to the applicant and licensee and the purpose of the licence

1. The name and address of the applicant, and, where the applicant is not the proposed licensee, the name and address of the proposed licensee being—

(*a*) the person who proposes to sell or supply the substance or article to persons who, for a medicinal purpose, may require to incorporate it in animal feeding stuffs, or who proposes to manufacture a substance or article for sale or supply to such persons who may require to incorporate it in animal feeding stuffs, or

(*b*) the person who proposes to obtain by purchase or otherwise a substance or article with a view to incorporation in animal feeding stuffs for a medicinal purpose.

2. The period for which the licence is desired, where it is for less than five years.

3. A statement of the activities to which the licence is to relate, and in particular whether it is one or more of the following—

(*a*) to sell or supply the substance or article to persons who for a medicinal purpose may require to incorporate it in animal feeding stuffs,

(*b*) to manufacture it for sale or supply to the persons described in subparagraph (*a*) of this paragraph,

(*c*) to obtain by purchase or otherwise a substance or article with a view to incorporating it in animal feeding stuffs for a medicinal purpose.

4. Where the applicant is a person who proposes to obtain by purchase or otherwise a substance or article with a view to incorporation in animal feeding stuffs for a medicinal purpose, the name and address of the person from whom it is to be purchased or otherwise obtained, and whether it is to be imported.

Particulars relating to the substance or article

5. The name or proposed name under which the substance or article is to be sold or supplied.

6. A statement of the specification of the substance or article other than as required by paragraphs 7, 8 and 10 of this part of this Schedule.

7. A description of the pharmaceutical form in which the substance or article is to be incorporated in animal feeding stuffs.

8. A statement of the qualitative and quantitative composition of the substance or article covering—

(*a*) all active constituents,

(*b*) all colouring matter, flavouring agents and perfumes, and

(*c*) all other constituents.

9. 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, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub paragraphs (*a*) and (*b*) of this paragraph, the proprietary designation.

10. The specification of all constituents whether active or not. Where the constituent is the subject of a monograph, a reference to the monograph name may be given instead of the specification.

11. The chemical structural formula for each active constituent where known. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of the formula.

12. A description of the method of manufacture or assembly of the substance or article.

13. A description of the method of manufacture of each active constituent. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of a description.

14. A statement whether precautions will be taken during manufacture or assembly to control the quality of the substance or article and whether the proposed licensee will be responsible for deciding that any batch of the substance or article is of acceptable quality for sale, supply or exportation, and, if not, who will be responsible.

15. In the case of all constituents whether active or not, a description of the quality control procedures and methods to be applied to ensure compliance with the specification.

16. A description of the procedures and methods to be used to ensure the uniformity of the substance or article in the process of manufacture or assembly and evidence of the stability and the grounds for any proposed shelf-life of the substance or article.

17. Particulars of the methods to be employed during manufacture or assembly for determining the identity, purity and potency of the substance or article and the address of the premises where such procedures are to be carried out.

18. A description of the nature of the containers to be used for the substance or article and a statement of any special directions necessary for storage and transport.

19. (*a*) a description of the feeding stuff, and

(*b*) data on any relevant compatibilities or incompatibilities of the substance or article known to the proposed licensee with other substances or articles, on its stability in animal feeding stuffs and on methods of incorporation and rates of inclusion in animal feeding stuffs, and

(*c*) a description of the method of analysis used to determine whether or not the substance or article has been correctly incorporated, and to determine the rates of inclusion in animal feeding stuffs.

20. Particulars of the indications suggested by the proposed licensee for the administration of the substance or article when incorporated in animal feeding stuffs.

21. Any directions, contra-indications and warnings proposed, and the basic particulars of the information proposed to be included on the container label, on the package label and in any leaflet to be inserted in the package, or in other informative literature.

Regulation 4(5)

SCHEDULE 2

PARTICULARS REQUIRED ON AN APPLICATION FOR THE ISSUE OF A CLINICAL TRIAL CERTIFICATE

Particulars relating to the applicant, the certificate holder and the activities to which the certificate relates

1. The name and address of the applicant, and, where the applicant is not the proposed certificate holder, the name and address of the proposed certificate holder.

2. The period for which the certificate is desired, where it is for less than two years.

3. A statement of the activities to which the certificate is to relate, and in respect of each medicinal product which is the subject of the application, whether it is one or more of the following—

(*a*) to sell or supply the medicinal product for the purpose of a clinical trial,

(*b*) to procure the sale or supply of the medicinal product for the purpose of a clinical trial,

(*c*) to procure the manufacture or assembly of the medicinal product for sale or supply for the purpose of the clinical trial and whether or not in addition to the purpose specified in subparagraphs (*a*) or (*b*) of this paragraph.

4. Whether in respect of each medicinal product which is the subject of the application it is to be sold or supplied for the purposes of the trial—

(*a*) to practitioners,

(*b*) to persons engaged in providing hospital services, or

(*c*) otherwise.

5. (*a*) The name and address of any person in the United Kingdom other than the proposed certificate holder taking part in the manufacture or assembly of each medicinal product, and

(*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 to be imported, and

(*c*) a statement of the relevant manufacturing or assembling operations, and

(*d*) the address of the place or proposed place of manufacture or assembly.

6. Where the activity is to procure the sale or supply of any medicinal product, the name and address of the person selling or supplying the medicinal product for the purposes of the clinical trial.

Particulars relating to each medicinal product which is the subject of the application

7. The name or proposed name of each medicinal product or the proposed certificate holder's code designation where the medicinal product has not been given a name.

8. A statement of the specification of each medicinal product other than as required by paragraphs 9, 10 and 12 of this Schedule.

9. A description of the pharmaceutical form in which each medicinal product is to be administered to human beings.

10. A statement of the qualitative and quantitative composition of each medicinal product covering—

(*a*) all active constituents,

(*b*) all colouring matter, flavouring agents and perfumes, and

(*c*) all other constituents.

11. 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, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub paragraphs (*a*) and (*b*) of this paragraph, the proprietary designation.

12. The specification of all constituents whether active or not. Where the constituent is the subject of a monograph, a reference to the monograph name may be given instead of the specification.

13. The chemical structural formula for each active constituent, where known. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of the formula.

14. A description of the method of manufacture of each medicinal product.

15. A description of the method of manufacture of each active constituent. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of a description.

16. In the case of all constituents, whether active or not, a description of the quality control procedures and methods to be applied to ensure compliance with the specification.

17. A description of the procedures and methods to be used to ensure the uniformity of each medicinal product in the process of manufacture or assembly and evidence of the stability of the product.

18. Particulars of the methods to be employed during manufacture for determining the identity, purity and potency of each medicinal product and the address of the premises where such procedures are to be carried out.

19. A description of the nature of the containers to be used for each medicinal product and a statement of any special directions necessary for storage and transport.

20. A description of the clinical use to be investigated and an outline of the proposed trial.

21. Particulars of the proposed dose or dosage, methods and routes of administration.

22. A statement of the directions, contra-indications and warnings proposed by the applicant in relation to the trial of each medicinal product.

23. Copies 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 proposed certificate holder 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.

Regulation 4(6)

SCHEDULE 3

PARTICULARS REQUIRED ON AN APPLICATION FOR THE ISSUE OF AN ANIMAL TEST CERTIFICATE

Particulars relating to the applicant, the certificate holder and the activities to which the certificate relates

1. The name and address of the applicant, and, where the applicant is not the proposed certificate holder, the name and address of the proposed certificate holder.

2. The period for which the certificate is desired, where it is for less than two years.

3. A statement of the activities to which the certificate is to relate, and whether it is—

(*a*) to sell or supply the medicinal product for the purpose of a medicinal test on animals, or

(*b*) to procure the sale or supply of the medicinal product for the purpose of a medicinal test on animals, or

(*c*) to procure the manufacture or assembly of the medicinal product for sale or supply for the purpose of the medicinal test on animals and whether in addition to the purpose specified in sub paragraphs (*a*) or (*b*) of this paragraph,

(*d*) to administer the medicinal product or the substance or article for the purpose of a medicinal test on animals.

4. A statement of the purpose of the medicinal test on animals and whether it is—

(*a*) to administer a medicinal product of a particular description to animals, where there is evidence that medicinal products of that description have effects which may be beneficial to, or otherwise advantageous in relation to those animals, and the product is administered for the purpose of ascertaining whether, or to what extent, it has those or any other effects, whether advantageous or otherwise, or

(*b*) to administer a medicinal product to animals in circumstances where there is no such evidence as is mentioned in the preceding sub paragraph, and the product is administered for the purpose of ascertaining whether, or to what extent, it has any effects relevant to a medicinal purpose, or

(*c*) to administer a substance or article, other than a medicinal product, to animals for the purpose of ascertaining whether it has any effects relevant to a medicinal purpose, whether there is evidence that it has effects which may be beneficial to, or otherwise advantageous in relation to those animals or not.

5. Whether the medicinal product or the substance or article is to be sold or supplied for the purposes of the test—

(*a*) to practitioners,

(*b*) to persons engaged in agriculture,

(*c*) to persons engaged in fish farming, or

(*d*) otherwise.

6. (*a*) The name and address of any persons in the United Kingdom other than the proposed certificate holder, taking part in the manufacture or assembly of the medicinal product or the substance or article,

(*b*) in the case of an imported medicinal product or an imported substance or article, the name and address of the manufacturer and assembler of the medicinal product or the substance or article in the form in which it is to be imported, and where the proposed certificate holder has procured or is to procure the importation, the name and address of the importer of the medicinal product or the substance or article,

(*c*) a description of the relevant manufacturing or assembling operations, and

(*d*) the address of the place or proposed place of manufacture or assembly.

7. Where the activity is to procure the sale or supply of the medicinal product or the substance or article, the name and address of the person selling or supplying the medicinal product or the substance or article for the purposes of the medicinal test on animals.

8. The name or proposed name of the medicinal product or the substance or article, or the proposed certificate holder's code designation where the medicinal product or the substance or article has not been given a name.

Particulars relating to the product

9. A statement of the specification of the medicinal product or the substance or article other than as required by paragraphs 10, 11 and 13 of this Schedule.

10. A description of the pharmaceutical form in which the medicinal product or the substance or article is to be administered to animals, and whether or not after incorporation in animal feeding stuffs.

11. A statement of the qualitative and quantitative composition of the medicinal product or the substance or article covering—

(*a*) all active constituents,

(*b*) all colouring matter, flavouring agents and perfumes, and

(*c*) all other constituents.

12. 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, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub paragraphs (*a*) and (*b*) of this paragraph, the proprietary designation.

13. The specification of all constituents whether active or not. Where the constituent is the subject of a monograph, a reference to the monograph name may be given instead of the specification.

14. The chemical structural formula for each active constituent where known. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of the formula.

15. A description of the method of manufacture or assembly of the medicinal product or the substance or article.

16. A description of the method of manufacture of each active constituent. Where the active constituent is the subject of a monograph, a reference to the monograph name may be given instead of a description.

17. In the case of all constituents, whether active or not, a description of the quality control procedures and methods to be applied to ensure compliance with the specification.

18. A description of the procedures or methods to be used to ensure the uniformity of the medicinal product or the substance or article in the process of manufacture or assembly and evidence of the stability of the medicinal product or the substance or article.

19. Particulars of the methods to be employed during manufacture or assembly for determining the identity, purity and potency of the medicinal product or the substance or article and the address of the premises where such procedures are to be carried out.

20. A description of the nature of the containers to be used for the medicinal product or the substance or article, and a statement of any special directions necessary for storage and transport.

21. In the case of an application relating to a medicinal product or a substance or article to be incorporated in any animal feeding stuff—

(*a*) a description of the feeding stuff, and

(*b*) data on any relevant compatibilities or incompatibilities of the medicinal product or the substance or article known to the proposed certificate holder with other substances or articles, on its stability in animal feeding stuffs and on methods of incorporation and rates of inclusion in animal feeding stuffs, and

(*c*) a description of the method of analysis used to determine whether or not the medicinal product or the substance or article has been correctly incorporated, and to determine the rates of inclusion in animal feeding stuffs.

22. Where the purpose of the medicinal test is as stated in sub paragraph (*a*) of paragraph 4 of this Schedule, a description of the effects to be investigated and an outline of the proposed medicinal test. Where the purpose of the medicinal test is as stated in sub paragraph (*b*) or (*c*) of paragraph 4, an outline of the proposed medicinal test.

23. Particulars of the proposed dose or dosage, methods and routes of administration.

24. A statement specifying where and by whom it is proposed that the medicinal test shall be carried out and the arrangements for the supervision of the performance of the medicinal test.

25. A statement of the directions, contra-indications and proposed warnings put forward by the proposed certificate holder in relation to the medicinal test of the medicinal product or the substance or article.

26. Copies of reports and evaluations of any experimental and biological studies and of other preclinical, clinical or laboratory studies carried out with the medicinal product or its constituents or the substance or article or its constituents which in the view of the proposed certificate holder are relevant to the assessment of the safety, quality or efficacy of the medicinal product or the substance or article, together with references to relevant publications or other medicinal tests on animals.

27. Particulars of any data bearing on—

(*a*) the efficacy in animals of the medicinal product or the substance or article,

(*b*) the places at which the medicinal test is to be performed,

(*c*) considerations of safety for the purposes of the Act.

28. Particulars of the safety precautions for the performance of the medicinal test.

29. Particulars of the arrangements for the disposal of the animals used in the medicinal test, their carcases and their produce.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations made under the Medicines Act 1968 relate to applications for the grant of product licences other than product licences of right, and the issue of clinical trial certificates and animal test certificates, other than certificates issued under section 37(4) of the Act, with respect to medicinal products and certain substances and articles, including those for incorporation in animal feeding stuffs. They prescribe the form and manner in which such applications are to be made, and specify the information, documents, samples and other material that shall accompany each application.