SCHEDULE 1

Regulation 4(1) and (2)

INFORMATION, DOCUMENTS, SAMPLES AND OTHER MATERIAL REQUIRED IN RESPECT OF APPLICATIONS

(a) (a) The name or corporate name of and the permanent address of—

(i) the person responsible for placing the product on the market in the United Kingdom,

(ii) the manufacturers and the sites involved in the different stages of the manufacture (including the manufacturer of the finished product and the manufacturers of the active ingredients), and

(iii) where relevant, the importer;

(b) where the licence applied for is required solely for the purpose of exporting a product, the name or corporate name of and the permanent address of the exporter; and

(c) in relation to any product in respect of which section 7(2) of the Act applies by virtue of section 43 of the Act, a description of the circumstances in which the relevant seller, supplier or exporter will sell, supply or export the product if he is not named under sub-paragraph (a) above.

2. The name of the product, that is to say, the brand name, or common name together with a trade mark, or name of the manufacturer, or scientific name together with a trade mark or name of the manufacturer.

3. The qualitative and quantitative particulars of all the constituents of the product together with details of any relevant data concerning the container and, where appropriate, its manner of closure, and details of devices with which the medicinal product will be used or administered and which will be delivered with the product.

4. A brief description of the method of preparation.

5. Particulars of the therapeutic indications, contra-indications and side-effects.

6. Particulars of the posology, pharmaceutical form, method and route of administration and expected shelf-life.

7. A description, drawn up and signed by experts, of the control methods employed by the manufacturer (indicating the qualitative and quantitative analysis of the constituents and of the finished product, special tests, for example sterility tests, tests for the presence of pyrogenic substances and for the presence of heavy metals, stability tests, biological and toxicity tests, and controls carried out at an intermediate stage of the manufacturing process).

8. Subject to Schedule 2, particulars, drawn up and signed by experts, of the results of:

(a) physico-chemical, biological or microbiological tests;

(b) pharmacological and toxicological tests;

(c) clinical trials;

including all relevant details of any incomplete or abandoned pharmacotoxicological or clinical test or trial.

9. A summary of the product characteristics which shall contain the following information:

(a) the name of the product;

(b) its qualitative and quantitative composition in terms of the active ingredients, knowledge of which is essential for proper administration of the product, using international non-proprietary names or, where there is no such name, the usual common name or chemical description;

(c) its pharmaceutical form;

(d) clinical particulars covering—

(i) therapeutic indications,

(ii) posology and method of administration for adults and, where necessary, for children,

(iii) contra-indications,

(iv) special warnings,

(v) special precautions for use and, in relation to any immunological medicinal product to which Directive 89/342/EEC(**1**) applies, information regarding any special precautions to be taken by persons handling the product and persons administering it to patients, together with any precautions to be taken by the patient,

(vi) interaction with other medicaments and other forms of interaction,

(vii) use during pregnancy and lactation,

(viii) effects on ability to drive and to use machines,

(ix) undesirable effects (including their frequency and seriousness),

(x) overdose (covering symptoms, emergency procedures and antidotes);

(e) its pharmacological properties and, insofar as this information is useful for therapeutic purposes, pharmacokinetic particulars;

(f) pharmaceutical particulars covering—

(i) qualitative composition in terms of the excipients used,

(ii) major incompatibilities,

(iii) shelf-life, when necessary after reconstitution of the product or when the container is opened for the first time,

(iv) special precautions for storage,

(v) nature and composition of the container,

(vi) special precautions for disposal of unused products or waste materials derived from such products, if appropriate,

(vii) name or style and permanent address or registered place of business of the holder of the licence;

(g) in relation to any radiopharmaceutical to which Directive 89/343/EEC(**2**) applies—

(i) full details of internal radiation dosimetry, and

(ii) additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready to use pharmaceutical will conform with its specifications; and

(h) in relation to any indications to which sub-paragraphs (a) and (b) of paragraph 22 below apply, a statement drawing the attention of persons qualified to prescribe or supply the product to the fact that the particulars available concerning the product are as yet inadequate in certain specified respects.

10. A copy of the manufacturing authorisation as defined in Article 16 of Directive 75/319/EEC(**3**), and any other relevant document showing that the manufacturer is authorised in his own country to produce products.

(**1**) OJ No.L142, 25.5.89, p.14.
(**2**) OJ No.L142, 25.5.89, p.16.
(**3**) OJ No.L147, 9.6.75, p.13.

11. A copy of any authorisation obtained in a member State other than the United Kingdom or in a third country to place the relevant product on the market and of all the summaries of product characteristics in accordance with Article 4a of the 1965 Directive as approved by member States, and a list of countries in which an application has been submitted.

12. An expert's report (stating, where applicable, the grounds for using published references which the applicant claims to be entitled to use in accordance with paragraphs 1 to 4 of Schedule 2), signed and dated by the expert, on—

(a) the chemical, pharmaceutical and biological documentation;

(b) the pharmacotoxicological documentation;

(c) the clinical documentation;

respectively.

13. Brief information about the educational background, training and occupational experience of each expert, and a declaration as to his professional relationship to the applicant.

14. One or more samples or mock-ups of the sales presentation, the outer packaging, the immediate packaging, the labels, and the package leaflet (or draft package leaflet) where one is to be enclosed.

15. A statement of the number of volumes of documentation submitted in support of the application.

16. A statement as to any samples provided.

17. Where the applicant is, by virtue of paragraph 8 above, required to provide particulars of the results of any safety test falling within Part 3, paragraph 1.1, second sub-paragraph of the Annex to Directive 75/318/EEC(**4**), a copy of any certificate issued by the laboratory which carried out the test to the effect that the test was carried out in conformity with the principles of good laboratory practice referred to in that sub-paragraph.

18. Where the applicant is, by virtue of paragraph 8 above, required to provide particulars of the results of any clinical trial, a summary of the arrangements proposed to be made for the archiving of documentation of the trial in accordance with Part 4, paragraph B.2 of the Annex to Directive 75/318/EEC, including (in particular) the arrangements proposed for ensuring that any change of ownership in the relevant data is documented and that all relevant data and documents will be made available to the licensing authority if required.

19. A statement indicating—

(a) which of the following should apply to the product, that is to say that the product should be available:

(i) on prescription only (that is to say, that it should be subject to restrictions imposed by section 58(2)(a) or 60(1)(b) of the Act);

(ii) only from a pharmacy (that is to say, that it should be subject to a restriction under section 52 or section 53 of the Act to the effect that it may be sold only at a registered pharmacy, but not subject to the restrictions imposed by section 58(2)(a) or 60(1)(b) of the Act); or

(iii) on general sale (that is to say, that it should not be subject to any of the restrictions referred to in paragraphs (i) and (ii) above); and

(b) what, if any, provisions of the licence are proposed concerning the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product).

(**4**) OJ No.L147, 9.6.75, p.1. A new Annex was substituted by Directive 91/507/EEC (OJ No.L270, 26.9.91, p.32).

20. If the product is already authorised in other countries—

(a) information in respect of adverse drug reactions to the product and products containing the same active ingredient (in relation to the usage rates if possible) and information from worldwide studies relevant to the safety of the product;

(b) in the case of vaccines, information on the monitoring of vaccinated subjects to evaluate the prevalence of the disease in question as compared to non-vaccinated subjects, when such information is available; and

(c) for allergen products, details of response in periods of increased antigen exposure.

21. In relation to any generator to which Article 3 of Directive 89/343/EEC(**5**) applies—

(a) 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

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

22. Where the applicant, in relation to all or any particular therapeutic indications, omits any information by virtue of paragraph 5 of Schedule 2—

(a) detailed proposals for the programme of studies referred to in that paragraph (including a proposed period for carrying them out) for the purposes of a reassessment of the benefit/risk profile in relation to those indications; and

(b) a statement as to any proposal that the product in question should be administered for those indications only under strict medical supervision, possibly in a hospital, and, for a radiopharmaceutical to which Directive 89/343/EEC applies, by an authorized person.

23. Where the licence applied for is required solely for the purpose of exporting a product, a statement to that effect.

24. A statement indicating that the applicant agrees that the licence applied for is to be subject to the relevant standard provisions prescribed by the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**6**) or indicating which, if any, of those provisions it is desired shall be excluded from the licence, and what, if any, modifications it is desired should be made to any of those provisions.

25. All other information which is relevant to the evaluation of the product, whether favourable or unfavourable to it.

(**5**) OJ No.L142, 25.5.89, p.16.
(**6**) S.I.1971/972; the relevant amending regulations are S.I.1972/1226, 1974/1523, 1977/675, 1977/1039, 1977/1053, 1983/1730, 1992/2846, 1992/3272, 1993/833 and 1993/2539.