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STATUTORY INSTRUMENTS

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**1993 No. 2538**

**MEDICINES**

**The Medicines (Applications for Grant of Product Licences—Products for Human Use) Regulations 1993**

*Made* - - - - - *21st October 1993*  
*Laid before Parliament* *28th October 1993*  
*Coming into force* *29th November 1993*

**THE MEDICINES (APPLICATIONS FOR GRANT OF PRODUCT LICENCES—PRODUCTS FOR HUMAN USE) REGULATIONS 1993**

1. Citation, commencement and interpretation
  2. Application of these Regulations
  3. Manner of applications
  4. Material to be contained in or accompany an application
  5. Amendment of the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971
- Signature

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SCHEDULE 1 — INFORMATION, DOCUMENTS, SAMPLES AND OTHER MATERIAL REQUIRED IN RESPECT OF APPLICATIONS

1. (a) The name or corporate name of and the permanent...
2. The name of the product, that is to say, the...
3. The qualitative and quantitative particulars of all the constituents of...
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...
7. A description, drawn up and signed by experts, of the...
8. Subject to Schedule 2, particulars, drawn up and signed by...
9. A summary of the product characteristics which shall contain the...
10. A copy of the manufacturing authorisation as defined in Article...
11. A copy of any authorisation obtained in a member State...
12. An expert's report (stating, where applicable, the grounds for using...

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13. Brief information about the educational background, training and occupational experience...
14. One or more samples or mock-ups of the sales presentation,...
15. A statement of the number of volumes of documentation submitted...
16. A statement as to any samples provided.
17. Where the applicant is, by virtue of paragraph 8 above,...
18. Where the applicant is, by virtue of paragraph 8 above,...
19. A statement indicating— (a) which of the following should apply...
20. If the product is already authorised in other countries—
21. In relation to any generator to which Article 3 of...
22. Where the applicant, in relation to all or any particular...
23. Where the licence applied for is required solely for the...
24. A statement indicating that the applicant agrees that the licence...
25. All other information which is relevant to the evaluation of...

**SCHEDULE 2 — EXCEPTIONS TO THE REQUIREMENT TO PROVIDE PARTICULARS OF THE RESULTS OF TESTS AND TRIALS REFERRED TO IN PARAGRAPH 8 OF SCHEDULE 1**

1. Subject to paragraphs 2 to 4 below, the applicant shall...
2. Notwithstanding paragraph 1 above, the applicant shall provide particulars of...
3. Where the product is a new medicinal product containing known...
4. The applicant shall not be entitled by virtue of the...
5. Subject to compliance with paragraphs 19(a) and 22 of Schedule...
6. The applicant shall not be required under paragraph 8 of...

**SCHEDULE 3 — CIRCUMSTANCES IN WHICH CERTAIN PARTICULARS MAY BE PROVIDED BY A MANUFACTURER (OTHER THAN THE APPLICANT) OF CERTAIN ACTIVE INGREDIENTS**

1. In the case of— (a) an active ingredient not described...
2. Paragraph 1 of this Schedule shall not apply unless the...

Explanatory Note